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(54) Title: SHEET-LIKE DEVICES

(57) Abstract: The present invention relates to pre-formed, unilamellar, sheet-like devices (10, 110, 210, 310, 410, 510, 610, 710, 810) for delivering benefit agents to the skin, hair or nails. The devices are patches or masks for cosmetic or therapeutic use. The devices have a non-planar topography on at least one surface (14, 114, 214, 314, 414, 514, 614, 714, 814; 16, 116, 216, 316, 416, 516, 616, 716, 816) and are less obtrusive. The present invention also encompasses methods of producing such devices.

# SHEET-LIKE DEVICES

## Technical Field

The present invention relates to novel pre-formed, unilamellar sheet-like devices. In particular it relates to pre-formed, unilamellar sheet-like devices which are patches or masks, comprising at least one polymeric gel forming agent for delivering benefit agents to the skin, hair or nails. Said devices are suitable for topical delivery of at least one benefit agent and display improved mechanical properties such as strength and flexibility. Further, the devices of the present invention are unobtrusive and conform to the contours of a target surface when applied.

## Background of the Invention

The benefits of using a patch or mask device comprising a polymeric gel forming agent instead of creams and lotions and the like, to cosmetically treat the skin, hair or nails, or to promote the healing of burns or wounds has been recognised in the art. A variety of cosmetic patches or devices are commercially marketed or described as being useful for the delivery of skin care actives such as vitamins, anti-acne actives, moisturisers and the like. Patches and devices have also been described in the literature and marketed in the medical field as a useful means for the transdermal administration of drugs. However, many of these patches or devices suffer drawbacks in their physical product forms resulting in undesirable in-use characteristics as perceived by the consumer or wearer. For example, some patches or devices may be too wet or sticky, as the gel forming agents comprising the patch or device do not form a solid gel structure and as a result, the patches or devices are difficult to handle and apply to the skin. Others are strongly adhesive, tight and uncomfortable to wear and remove, and many patches do not provide an effective release and penetration of benefit agents.

Some patches or devices require formation *in situ* on the skin and are therefore messy to apply. For example, US-A-4,291,025 relates to a thermally reversible agar gel topical dressing comprising 5 to 12% agar, 20 to 75% diethylene glycol and water to 100%; and

methods for preparing said dressing. The compositions may additionally comprise gel strengthening agents and special purpose ingredients (e.g. vitamins, antibiotics). According to one aspect of the invention of US-A-4,291,025, solid, high strength, yieldable agar gels are prepared and then subdivided into smaller pellets or pieces. According to another aspect, the agar gel is then converted into a sol upon heating, the sol is applied to the target skin and cooled *in situ* to form a removable gel form.

Further, some patches or devices are too dry or inflexible and therefore do not conform well to the contours of the surface to which they are applied. For example, EP-A-161 681 discloses gel plates comprising a polysaccharide and an aqueous solution of a polyhydric alcohol. Preferred polysaccharides for the gel plates are a blend of carrageenan and a galactomannan, or carrageenan alone. The compositions optionally comprise medical components such as skin stimulants, antiphlogistics, analgesics and antibiotics. The gel plates are disclosed as being transparent or inconspicuous, having a refreshing feeling and good adhesion, as well as being sufficiently elastic, stretchable and strong.

Flexibility and strength are further important features of a gelled device. WO97/17944 discloses cosmetic formulations made up of a gel material consisting of a balanced mixture of polysaccharides containing a soluble alginate (0.1-5%), agar (0.01-0.5%), pectin (0.01-0.5%), xanthan gum (0.05-1%) with the balance consisting of water. The gel material is optionally enriched with water-soluble or water-dispersible active ingredients. The gel material may be processed to form a structured gel which is disclosed as being easy to handle and well adapted to the skin surface.

WO90/14110 discloses pharmaceutical preparations which may take the form of a self-supporting slab, pad or wafer of a desired size, shape and thickness comprising a water insoluble alginate and suspending agents such as xanthan gum alone, or xanthan gum in combination with locust bean gum. Gellan gum is also disclosed as a further useful suspending agent. The suspending agents in the preparations may also act as gel forming agents. The preparations optionally comprise anti-inflammatory agents, or the antiseptic agent, iodine. The slab or wafer forms of a preparation may be flexible and applied onto a

plastic backing to form an integral surgical dressing, with the gel either exposed or covered with a gauze.

US-A-4,318,746 relates to a gel comprising at least 0.5% of a first polymer that disperses, dissolves or hydrates in hot water and that forms, or can be made to form, a rigid gel on cooling, at least 2% of a second polymer that is insoluble in hot water and that dissolves or hydrates on cooling and is compatible with the first polymer, and water. The document describes the gel as being firm, cohesive and adhesive and useful for example, as an electrode or for the topical administration of drugs. The document outlines that one of the advantages of the gel is that it is relatively rigid and adhesive at temperatures below 60-65°C.

JP-A-63-200760 discloses a bi-layered patch comprising a gelled matrix and a support sheet (or backing). The description teaches that the skin-engaging surface of the gelled matrix is preferably flat. Alternatively, the skin-engaging surface may include a mesh-like array of channels (Figure 3), an imprint of a logo or the like (Figure 2), a substantially parallel arrangement of channels (Figure 5) or an array of projections (Figure 7). The gelled matrix comprises a protein (gelatin, casein, albumen or serecin) or a water-soluble polymer, to which an inorganic filler, a humectant, possibly a binder and/or a cross-linking agent is added. The bi-layered patch is made by casting into a mould of the desired shape.

WO98/17287 concerns a hollow flexible silicone cushion for treating keloid and hypertrophic scars, by developing a negative electric charge near the scar. The cushions may be made from textured silicone sheeting, the term "textured" being defined as an irregular surface containing, for example, corners, indentations or related textural features which may be regular or irregular in shape and appearance. It is taught that texturing results in a non-uniform distribution of charge. No method for texturing silicone sheeting is disclosed.

US-A-4,289,125 discloses polymeric sheets for use as burn dressings whose skin-facing surface, at least, is textured. It is taught that this is advisable to provide a reservoir for wound debris and for adherence to the wound area. Burn dressings with a textured

surface on one surface or on both surfaces are disclosed. Fig. 1D discloses a unilamellar device, in which both surfaces are textured. The fabric textured sheet acts as a skeleton, to carry polymer, which is then cured. Thereafter, the skeleton fabric sheet is removed by solvent leaching, leaving an integral unilamellar self-supporting polymeric sheet. Figures 5F-5I disclose a laminated device having one "textured" surface. This comprises a smooth surfaced polymeric membrane in which is partially embedded a material which will impart a fabric texture to its surface. The material to be embedded can be uncoated or coated gauze or mesh or the above-mentioned fabric sheets (with or without leaching of the skeleton sheet). Fig. 6D illustrates a non-laminated embodiment having one "textured" surface. The fabric material is stretched over an appropriate surface, to act as a skeleton to carry a membrane layer of polymer which forms a continuous phase with the polymer coating in the fabric material (see Fig. 6C). The fabric material may, thereafter, be leached.

WO94/02674 concerns a dual textured treatment pad comprising a paper layer laminated to a synthetic fiber, non-woven layer having a repeating pattern comprising at least two adjacent delineated regions simultaneously not having the same thickness or having regularly or irregularly spaced apertures. Dual texturing permits both gentle and vigorous cleansing from the same pad.

WO98/50085 concerns an article being, for example, a wound dressing or a target strip for a disposable diaper. The article comprises a substrate and a textured, matte-finish, low adhesion backsize coating. The document teaches that the matte-finish surface on a wound dressing is achievable by "mechanical action" and makes the dressing less visible when applied to the skin.

US-A-5,026,446 concerns a physically abraded target strip for disposable diapers. The physical abrasion is to improve adhesion of adhesive closure tabs to the target strip.

While the above-mentioned patches or sheets from the cosmetic and medical field provide advances in attaining desirable physical and in-use characteristics, the documents do not describe self-supporting, pre-formed sheet-like devices which are unilamellar, wherein the devices have desirable mechanical properties of strength, robustness and flexibility, as

well as desirable in-use properties of ease of handling, unobtrusiveness and conformability to the contours of a target surface when applied.

It has now been surprisingly found that a pre-formed, unilamellar sheet-like device may be formulated as a self-supporting, high strength structure which is sufficiently flexible to conform to the contours of a target surface when applied. The devices according to a first aspect herein have a non-planar topography, the topography of which is selected according to the target surface of application, making them easy to handle and apply. For example, thicker ridges around the perimeter of the device facilitate ease of handling and robustness, whereas thinner regions fit better to target surfaces in areas of increased curvature. Additionally or alternatively, a textured surface on the surface of the device either distal, in use, the skin, hair or nails of a user makes the device less obtrusive. The desirable physical properties are achieved by selecting the chemical composition and rheological characteristics of the gelled devices with reference to the relationship between strength and flexibility and the desirable in-use characteristics are achieved by selecting a suitable non-planar topography being at least two adjacent delineated regions simultaneously not having the same mean thickness and/or a suitable textured surface or surfaces.

The preferred pre-formed, unilamellar sheet-like devices of the present invention display a low level of syneresis, which makes the devices moist to the touch and helps provide a cooling sensation. The surface liquid can facilitate adhesion of the devices to a target surface, thus obviating the need for either an additional adhesive overlying the gelled form or an adhesive coated substrate.

The present unilamellar sheet-like devices do not require supporting or strengthening by an occlusive or non-occlusive backing material often referred to as a substrate. However, a substrate, if present, may be combined with a unilamellar sheet-like device and would confer further support or strengthening. In addition, substrates may also be employed to prevent evaporation of active ingredients, or act as a means for adhering a device to the skin when an adhesive is coated around its periphery. A substrate may be impregnated with, adhered, or laminated to one surface of the device.

EP-B-507,160 relates to an external preparation for application to the skin comprising a drug retaining layer placed on a support wherein the drug retaining layer comprises lidocaine, and an adhesive gel base comprising 0.5% to 50% of a water soluble, high molecular weight substance, 20. to 70% ,water and 1 to 70 % of a water retaining agent. Suitable supports are described as flexible materials such as non-woven fabrics.

The substrate, if present to confer further support or strengthening, must be compatible with the gel. A substrate is not compatible with the gel if the gel delaminates from the substrate. Even when a gel composition is found having desirable flexibility and strength, difficulties may still be incurred in matching such a gel with a substrate which is compatible with these gel properties. Combining a flexible substrate with a flexible gel does not necessarily produce a flexible patch or mask device. Aside from the problem of delamination, many flexible substrates often display a degree of porosity such that the wet gel infiltrates the substrate and forms strong gel networks within its fibers. Such networks are thought to reduce the flexibility of the resultant device. Further, the substrate may not provide a patch or mask device with an unobtrusive appearance on the skin, hair, or nails. This will often depend on the choice of substrate and its characteristics.

The sheet-like devices herein are preferably patches or masks for cosmetic or therapeutic application.

## Summary of the Invention

The present invention relates, in a first aspect, to a pre-formed, unilamellar sheet-like device for delivering benefit agents to the skin, hair or nails, the device having a perimeter defining first and second spaced-apart surfaces; the device comprising at least one benefit agent and at least one polymeric gel forming agent; and the device having a non-planar topography on at least one of the first and second surfaces.

According to a second aspect of the present invention there is provided a pre-formed, unilamellar sheet-like device for delivering benefit agents to the skin, hair or nails, the device having a perimeter defining first and second spaced-apart surfaces; the device comprising at least one benefit agent and at least one polymeric gel forming agent; and the

device having a non-planar topography on at least one of the first and second surfaces, the non-planar topography comprising at least two adjacent delineated regions simultaneously not having the same mean thickness.

According to a third aspect of the present invention there is provided a pre-formed, unilamellar sheet-like device for delivering benefit agents to the skin, hair or nails, the device comprising at least one benefit agent and at least one polymeric gel forming agent; and the device having a perimeter defining first and second spaced-apart surfaces, the first surface being adjacent, in use, the skin, hair or nails, and the second surface having a non-planar topography, the non-planar topography comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm.

Devices of the invention having textured surfaces are preferably not just visibly textured but also textured to the touch.

The devices of the invention are suitable for topical application to the skin, hair or nails. They provide excellent in-use characteristics such as unobtrusiveness, comfort, fit, flexibility, visual appearance, strength, ease of handling and conformability upon topical application. Further, the devices described herein have excellent mechanical properties and form a high strength structure which is flexible and has a degree of elasticity. The preferred devices of the present invention show a low level of syneresis providing further in-use characteristics of hydration and moisturisation benefits upon topical application.

According to a fourth aspect of the invention there is provided a method of producing a pre-formed, unilamellar sheet-like device according to the first or second aspects of the invention, the method comprising the steps of providing a gel-forming mixture comprising at least one benefit agent and at least one gellable polymeric gel forming agent in a mould having at least one surface that is the negative image of the, or each, non-planar topography, the non-planar topography comprising at least two delineated regions simultaneously not having the same mean thickness or a textured surface that is the negative image of a texturing surface, the texturing surface having a texture defined by $R_a$ of greater than 10μm or both; and thereafter gelling the gel-forming mixture. In a

preferred embodiment, the mould has opposed texturing surfaces having a texture defined by $R_a$ of greater than 10μm, in order to imprint textured surfaces on opposed first and second surfaces of the device. More preferably, the mould is configured additionally to provide a non-planar topography comprising at least two delineated regions simultaneously not having the same mean thickness on at least one surface of the device, preferably the second surface which is that distal the skin, hair or nails when the device is in use.

In a fifth aspect, the present invention provides a method of producing a pre-formed, unilamellar sheet-like device according to the first or third aspect of the invention, the method comprising the steps of providing a gel-forming mixture comprising at least one benefit agent and at least one gellable polymeric gel forming agent in a mould, with a first mould surface which has a topography which is the negative image of the first device surface; bringing a second texturing surface into contact with the second device surface of the gel-forming mixture; gelling the gel-forming mixture; and removing the texturing surface from the device.

In a sixth aspect, the present invention provides a method of delivering at least one benefit agent to the skin, hair or nails, the method comprising contacting the skin, hair or nails with a device according to a first, second or third aspect of the invention, the device comprising at least one cosmetic benefit agent and at least one polymeric gel forming agent.

## Brief Description of the Drawings

Figs. 1a, 1b and 1c are plan, sectional perspective and perspective views of a first embodiment of a device according to a first or second aspect of the invention.

Figs. 2 and 3 are sectional views of second and third embodiments of a device according to the first or second aspect of the invention.

Fig. 4 is a sectional perspective, partial view of a fourth embodiment of a device according to the first, second or third aspect of the invention.

Fig. 5 is a sectional perspective, partial view of a second embodiment of a device according to the first or third aspect of the invention.

Fig. 6 is a schematic view of a fifth embodiment of a pre-formed, unilamellar sheet-like device according to a first or second aspect of the invention, *in situ* on a user's face.

Figs. 7a and 7b are plan and sectional views of the device of Figure 6.

Fig. 8 is a schematic view of a sixth embodiment of a device according to the first or second aspect of the invention, *in situ* on a user's face.

Fig. 9 is a plan view of the pre-formed, unilamellar sheet-like device of Figure 8.

Fig. 10 is a schematic view of a seventh embodiment of a device according to the first or second aspect of the invention, *in situ* on a user's face.

Fig. 11 is a plan view of the pre-formed, unilamellar sheet-like device of Figure 10.

Fig. 12 is a sectional view of an eighth embodiment of a device according to the invention, in its third aspect, wherein the device is textured on first and second surfaces.

## Detailed Description of the Invention

The pre-formed, unilamellar sheet-like devices of the present invention comprise at least one benefit agent and at least one polymeric gel forming agent, as well as various optional ingredients as indicated below. All levels and ratios are by weight of total composition of the device, unless otherwise indicated. When a substrate is used as an adjunct to the device, the total weight of the composition of the device is calculated without including the weight of the substrate.

The term "pre-formed" as used herein, means that the device so described is manufactured into a product form having a predetermined thickness, shape and size, wherein the device may be removed from any associated packaging and placed or draped onto the target surface by the fingers without the need to spread, rub or coat the target area with the product form. Devices herein are preferably packaged in a sealed, protective wrapper.

The term "sheet-like device", as used herein, means that the device described is a patch or mask for cosmetic or medical application wherein the patch is a continuous sheet, the

shape of which is pre-determined according to the specific area of skin, hair or nails to be treated and wherein the mask is a non-continuous sheet covering the facial area with apertures for the eyes, nose or mouth.

The term "unilamellar" as used herein, means that the device so described is a single layer which is self-supporting.

The term "non-planar topography" as used herein, means at least two adjacent delineated regions simultaneously not having the same mean thickness. Alternatively or additionally, the term "non-planar topography" means a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm. The term "$R_a$" as used herein means the surface-based average deviation from a best fit plane, described in detail below in the section headed "Methods of Evaluation".

The phrase "adjacent delineated regions simultaneously not having the same mean thickness" refers to adjacent regions of a device which are visually distinct and, when small scale thickness variations at particular points, such as that provided by the texturing described herein, are averaged out, their mean thicknesses are different.

The term "water-soluble" as used herein, means the ability of a gellable polymeric gel forming agent to dissolve in an aqueous solution either at room temperature or upon heating thereby forming a continuous phase.

The term "syneresis" as used herein, means the process whereby a gel contracts on standing with the exudation of liquid. Without being limited by theory, it is believed that gel compositions form 3-dimensional matrices which bind or encapsulate other ingredients of the composition. Syneresis is believed to involve a spontaneous separation of an initial homogeneous system into a coherent gel phase and a liquid. The exuded liquid is a solution whose composition depends upon that of the original gel. When a preferred device of the present invention is applied to a target area, the device loses some of its volume such that ingredients bound within the gel matrices such as water or benefit agents, are released towards, and penetrate the target area.

The term "polysaccharide" as used herein, means a naturally occurring or synthetically produced, linear, branched or cross-linked polymer of monosaccharide units, which swells when dispersed in water at low dry concentrations and gels the aqueous phase.

The term "percentage compression at rupture" as used herein, is a measure of the flexibility of a gel. Said method is described in detail below in the section headed "Methods of Evaluation".

The term "force to rupture" as used herein, is a measure of gel strength. Said method is described in detail below in the section headed "Methods of Evaluation".

The term "periodicity" as used herein, means a pattern of repeating units and is a measure of the distance between the start point and end point of a repeat unit of pattern.

The non-planar topography of devices of the present invention may have periodicity or no periodicity. Preferred periodic patterns are sinusoidal, saw tooth or conical. The preferred periodicity is from about 0.1mm to about 10mm, preferably from about 0.5mm to about 5mm. When the devices comprise textured first and second surfaces, the pattern on each surface can be the same or different and each pattern may have periodicity or no periodicity. If the patterns are both periodic the periodicity can be the same or different. In embodiments where the periodicity is the same, the pattern created by the periodicity on both surfaces may be aligned, so that peaks on one surface are directly opposed to peaks or troughs on the other, or staggered. Preferably, the pattern is staggered as it has been found that the devices are less visually obtrusive with staggered patterns.

In the drawings, similar numerals have been given to like parts.

Figs. 1a, 1b and 1c illustrate a first embodiment of a pre-formed, unilamellar sheet-like device according to the present invention, generally indicated as 10. The sectional perspective view of Fig. 1b is taken along line 1b-1b of Fig. 1a. The device 10 has a perimeter 12 defining first and second spaced-apart surfaces 14, 16. The device 10 has a non-planar topography on the second surface 16. The non-planar topography includes a delineated thickened region in the form of a rim 18 adjacent the perimeter 12 and a

delineated thickened region in the form of a ridge 20 intermediate the perimeter 12, as well as a delineated thinner region 22.

In use, it is intended that the substantially planar first surface 14 would be adjacent the skin, hair or nails of a user. It will, of course, be appreciated that both of the first and second surfaces 14, 16 might be provided with a non-planar topography (not shown). Equally, the non-planar topography might only be provided on the first surface 14 (not shown). The device 10 is suitable, for example, for delivering a benefit agent to the area of the skin under the eyes or around the mouth of a user.

The device 10 of Figs. 1a, 1b and 1c may have any suitable size, dependent on its intended use and product characteristics. The device is broadly crescent-shaped with overall dimensions, as defined by a notional rectangle bounding the shape, of about 60mm by about 27mm. The substantially crescent-shape has curved first and second apices proximal a first longitudinal side of the notional rectangle (not shown). The device 10 has dimensions of 13mm, 17mm, 20mm, 23mm and 21mm, respectively, at angles of 22.5°, 45°, 90°, 135° and 157.5° from the junction of the transverse mid-line of the notional rectangle with the first longitudinal side of the notional rectangle.

Fig. 2 illustrates a second embodiment of a pre-formed, unilamellar sheet-like device according to the first or second aspect of the invention, generally indicated as 110. The device 110 has a perimeter 112 defining first and second spaced-apart surfaces 114, 116, the device 110 having a non-planar topography comprising a delineated thickened region in the form of a rim 118 adjacent the perimeter 112 on the second surface 116, and a delineated thinner region 122, the delineated thickened and thinner regions 118, 122 simultaneously not having the same mean thickness. Rim 118 helps prevent tearing of the device 110 during handling and the thinner region 122 fits better, in use, to the skin of the user, in areas of greater curvature. Preferably, at least the thinner region 122 has, in addition, a non-planar topography on the second surface 116 comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm (not shown).

Fig. 3 illustrates a third embodiment of a device according to the first or second aspect of the invention, generally indicated as 210. The device 210 has a perimeter 212 defining first and second spaced-apart surfaces 214, 216, the device 210 having a non-planar topography comprising a delineated thickened region in the form of a ridge 220 intermediate the perimeter 212, and a delineated thinner region 222 adjacent the perimeter 212. Ridge 220 confers greater strength and resilience to handling and the thinner region 222 fits better, in use, to a target surface of greater curvature.

Fig. 4 illustrates, in a sectional perspective, partial view, a fourth embodiment of a pre-formed, unilamellar sheet-like device according to the first or second or a third aspect of the invention, generally indicated as 310. The device 310 has first and second spaced-apart surfaces 314, 316, the device 310 having a non-planar topography comprising a plurality of delineated thickened regions in the form of spaced-apart ridges 320 intermediate the perimeter (not shown), and a plurality of delineated thinner regions 322. As shown, although the device could alternatively be considered as being textured transverse to the ridges, there is no texturing along the length of the ridges. However, the illustrated non-planar topography may further comprise a textured surface, that is the negative image of a texturing surface, with texture defined by $R_a$ of greater than 10μm.

Fig. 5 shows, in a sectional perspective, partial view, a second embodiment of a pre-formed, unilamellar sheet-like device according to the first or third aspect of the invention, generally indicated as 410. The device 410 has first and second spaced-apart surfaces 414, 416, the first surface 414 being adjacent, in use, the skin, hair or nails and the second surface 416 having a non-planar topography comprising a textured surface that is the negative image of a texturing surface, with a texture defined by $R_a$ of greater than 10μm. It will be appreciated that the first and/or second surfaces 414, 416 may, in addition, have a non-planar topography comprising at least two delineated regions simultaneously not having the same mean thickness (not shown). It will also be appreciated that the first surface 414 may, optionally, have a non-planar topography comprising a textured surface that is the negative image of a texturing surface, with a texture defined by $R_a$ of greater than 10μm (not shown).

Figs. 6, 7a and 7b show a fifth embodiment of a pre-formed, unilamellar sheet-like device according to the first or second aspect of the invention, generally indicated as 510. The sectional view of Fig. 7b is taken along line 7b-7b of Fig. 7a. The device 510 has an irregular perimeter 512 defining first and second spaced-apart surfaces 514, 516. The device 510 has a non-planar topography comprising two adjacent delineated thinner and thickened regions 522, 524, respectively, simultaneously not having the same mean thickness. In the present embodiment, the non-planar topography is on the second surface 516. The thinner region 522 fits better in use, to the nasal area - an area of greater curvature.

Figs. 8 and 9 show a sixth embodiment of a pre-formed, unilamellar sheet-like device according to the first or second aspect of the invention, generally indicated as 610. The device 610 is a mask, shaped and dimensioned to substantially cover a user's face and has first and second spaced-apart surfaces 614, 616, the device 610 having a non-planar topography on the second surface 616 comprising at least two adjacent delineated thinner and thickened regions 622, 624, respectively, simultaneously not having the same mean thickness. The device 610 also comprises apertures 626 shaped and dimensioned to accommodate the eyes, nose and mouth of a user. The thinner regions 622 are spaced-apart about the perimeter 612 adjacent cut-away areas 628. In use, as illustrated in Fig. 8, the adjacent thinner regions 622 are contacted, so that the pre-formed, unilamellar sheet-like device 610 in the form of a mask substantially covers the face of a user, to deliver at least one benefit agent to the facial skin.

Figs. 10 and 11 show a seventh embodiment of a pre-formed, unilamellar sheet-like device according to the first or second aspect of the invention, generally indicated as 710. Device 710 is a mask, shaped and dimensioned to substantially cover the face of a user. Peripheral slits 730 are provided adjacent a perimeter 712. The device has a non-planar topography on a second surface 716, the non-planar topography comprising at least two adjacent delineated thinner and thickened regions 722, 724, respectively, simultaneously not having the same mean thickness. The thinner regions 722 are adjacent, in use, the eyes and nose/mouth region of a user, for the comfort of a user. Device 710 also includes

slits 732 and apertures 726, each shaped and dimensioned to accommodate the nose and mouth and eyes, respectively, of a user. In use, facing surfaces of peripheral slits 730 may be placed over each other, so that the pre-formed, unilamellar sheet-like device 710 in the form of a mask substantially covers the face of a user.

Fig. 12 illustrates an eighth embodiment, a device according to first, second and third aspects of the invention, generally indicated as 810. Device 810 has a perimeter 812 defining first and second spaced apart surfaces 814, 816, the device 810 having a non-planar topography comprising a delineated thickened region in the form of a rim 818 adjacent perimeter 812 on second surface 816, and a delineated thinner region 822, the delineated thickened and thinner regions 818, 822 simultaneously not having the same mean thickness. Additionally, the device has on both first and second surfaces 814, 816 a textured surface that is the negative image of a texturing surface, with a texture defined by $R_a$ of greater than 10μm.

Alternatively or additionally, the non-planar topography of the patch or mask device 10, 110, 210, 310, 410, 510, 610, 710, 810 may comprise a symbol (not shown). The symbol could take the form of, for example, a trade mark, being a logo device and/or a series of alphanumeric characters.

Preferably, the non-planar topography, being either a textured surface or at least two delineated regions simultaneously not having the same mean thickness or both, is provided on the second surface (distal, in use, the skin, hair or nails of a user) of the device. More preferably, non-planar topography, being a textured surface and at least two delineated regions simultaneously not having the same mean thickness, is provided on the second surface (distal, in use, the skin, hair or nails of a user) wherein additionally, non-planar topography, being a textured surface, is provided on the first surface of the device.

Polymeric Gel Forming Agents

As an essential component of the pre-formed, unilamellar sheet-like devices described herein, the devices comprise at least one polymeric gel forming agent. In general, the pre-formed, sheet-like devices of the present invention comprise less than 70%, preferably

less than 50%, more preferably less than 30% and especially less than 10% by total weight of a polymeric gel forming agent.

The at least one polymeric gel forming agent may be naturally or synthetically derived. The at least one polymeric gel forming agent can be self-gelling or may only form gels in combination with other substances. Alternatively, the at least one polymeric gel forming agent may be physically or chemically cross linked.

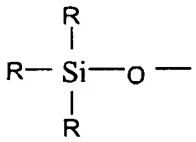
Polymeric gel forming agents may either be self-gelling or may only form gels in combination with other substances such as sugar, alcohol, or mono- or multi- valent salts. Mono- or multi- valent salts may additionally act as gel strengthening agents imparting added strength to the pre-formed, unilamellar sheet-like devices herein. Suitable cations may be selected from the mono- or multi- valent cations such as, for example, potassium, sodium, ammonium, zinc, aluminium, calcium and magnesium ions, or mixtures thereof. Suitable anions associated with the aforementioned cations may be selected from chloride, citrates, sulfate, carbonate, borate and phosphate anions, or mixtures thereof.

Physical cross linking refers to polymers having cross links which are not chemical covalent bonds but are of a physical nature such that there are areas in the device having high crystallinity or areas having a high glass transition temperature. Chemical cross linking refers to polymers which are linked by chemical bonds. Preferably, the polymer is chemically cross linked by radiation techniques such as thermal-, E beam-, UV-, gamma or micro-wave radiation. In addition when chemical crosslinks are formed in the system, a polyfunctional crosslinker and/or a free radical initiator may be present in the premix to initiate the crosslinking upon irradiation. Such components can be present preferably in quantities of up to 5% by weight.

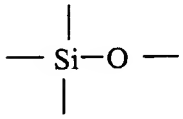
The polymeric gel forming agents are water soluble or non-water soluble. Preferably, the at least one polymeric gel forming agent is a water soluble gel forming agent. The polymeric gel forming agents may, alternatively, comprise non-water soluble polymeric gel forming agents, comprising silicone polymeric gel forming agents/silicones (organopolysiloxane resins) or block co-polymer thermoplastic elastomers.

Non-Water Soluble Polymeric Gel Forming Agents

Silicones may be described as soluble, hydroxyl-functional organopolysiloxane resins comprising $R_3SiO_{1/2}$ siloxane units and $SiO_{4/2}$ wherein R is a monovalent radical selected from hydrocarbon and halogenated hydrocarbon radicals having 1 to 20 carbon atoms. In the $R_3SiO_{1/2}$ and $SiO_{4/2}$ nomenclature, the 1/2 and 4/2 represent the number of half bonds on the molecule shown. For example in $R_3SiO_{1/2}$ there is one 1/2 bond which is on the oxygen, the other half of that bond being bonded to some other atom. This group may also be described as



Similarly, $SiO_{4/2}$ has four 1/2 bonds in the molecule shown, the other half of each bond being bonded to some other molecule. This group may also be described as



The term "soluble resin" as used herein, means that the gellable organopolysiloxane can be dissolved substantially completely, in either a hydrocarbon liquid such as benzene, toluene, xylene, heptane and the like or in a silicone liquid such as cyclic or linear poly-diorganosiloxanes. Preferably the resin is soluble in the silicone fluid.

In the formula for the silicone resin, R denotes a monovalent radical selected from hydrocarbon and halogenated hydrocarbon radicals, preferably having less than 20 carbon atoms, and most preferably having from 1 to 10 carbon atoms. Examples of suitable R radicals include alkyl radicals, such as methyl, ethyl, propyl, pentyl, octyl, undecyl, octadecyl and others; cycloaliphatic radicals, such as cyclohexyl; aryl radicals such as phenyl, tolyl, xylyl, benzyl, alpha-methyl styryl, 2-phenylethyl and others; alkenyl radicals such as vinyl; and chlorinated hydrocarbon radicals such as 3-chloropropyl, dichlorophenyl and others.

To enhance the solubility of the silicone resin in the silicone fluid, it is desirable to select the predominant organic radicals of the silicone resin to match the predominant organic radicals of the silicone fluid. Preferably, at least one-third, and more preferably substantially all, R radicals in the formula for the silicone resin are methyl radicals. Examples of preferred $R_3SiO_{1/2}$ siloxane units include $Me_3SiO_{1/2}$ and $PhMe_2SiO_{1/2}$ and $Ph_2MeSiO_{1/2}$ where Me denotes methyl and Ph denotes phenyl.

It is preferred that the ratio of $R_3SiO_{1/2}$ siloxane units to $SiO_{4/2}$ units has a molar ratio of 0.5 to 1.2, respectively. It is further preferred that the mole ratio of the total $R_3SiO_{1/2}$ siloxane units to $SiO_{4/2}$ units be between 0.6 and 0.8.

The silicone resin can be prepared by well known methods. It is preferably prepared by the silica hydrosol capping process of US-A-2,676,182 (Daudt et al.) as modified by US-A-3,627,851 (Brady) and US-A-3,772,247 (Flannigan); each patent being incorporated herein by reference to teach how to prepare soluble organopolysiloxanes which are useful in pre-formed, unilamellar sheet-like devices of the invention. The resulting resin can be used without further modification or it can be capped with trialkylsilyl groups to reduce the silanol content. This can be accomplished by well known methods, such as reacting the resin with a compound such as trimethylchlorosilane or hexamethyldisilazane.

The silicone fluid is preferably a hydroxyl-terminated diorganopolysiloxane polymer. The repeat units of the silicone fluid are $R_2SiO_{2/2}$ siloxy units wherein R is independently selected from the same hydrocarbon and halogenated radicals as defined above for the silicone resin. In general, the silicone fluid can be comprised of a single polymer or copolymer or it can be a mixture of two or more such polymers. The silicone fluid can be a liquid or gum at 25°C. It is preferred that at least 50%, and preferably at least 85%, of the organic radicals along the chain of the silicone fluid are methyl radicals, which can be distributed in any manner in the silicone fluid. Further, the silicone fluid can comprise up to about 10 mole percent of siloxane branching sites.

The silicone resin is preferably employed in amount of from about 40 to 70 parts by weight in the pre-formed, unilamellar sheet-like device, and the silicone fluid is employed

from about 30 to about 60 parts by weight, wherein the total parts of the silicone resin and the fluid are 100 parts. It is usually preferred that the silicone resin be employed from about 50 to 60 parts by weight, and correspondingly, the silicone fluid be employed from about 40 to 50 parts by weight, wherein the total parts by weight equals 100. The silicone resin and silicone fluid may be blended or condensed together to produce the pre-formed, unilamellar sheet-like device. Methods of condensing together the silicone resin and silicone fluid are well known in the art.

One preferred class of silicone resins consists of a mixture of a trimethylsilyl-endblocked polysilicate resin such as a silicone resin consisting of a benzene-soluble resinous copolymer containing silicon-bonded hydroxyl radicals and consisting essentially of triorganosiloxy units of the formula $R^1_3SiO_{½}$ and tetrafunctional siloxy units of the formula $SiO_{4/2}$ in a ratio of about 0.6 to 0.9 triorganosiloxy units for each tetrafunctional siloxy unit present in the copolymer, wherein $R^1$ is a monovalent organic radical independently selected from hydrocarbon radicals of from 1 to 6 carbon atoms; and a silanol-endcapped polydiorganosiloxane fluid such as a polydimethylsiloxane fluid. US-A-2,736,721 to Dexter et al. and US-A-2,814,601 to Currie et al. are hereby incorporated by reference to teach of such or similar resins.

Another suitable class are those in US-A-2,857,356 (Goodwin, Jr.), which is hereby incorporated by reference, or resins similar to those in Goodwin. US-A-2,857,356 discloses a silicone which consists of a mixture of ingredients comprising (i) a co-hydrolysis product of a trialkyl hydrolyzable silane and alkyl silicate, wherein the co-hydrolysis product contains a plurality of silicon-bonded hydroxy groups; and (ii) linear, high viscosity organopolysiloxane fluid containing silicon-bonded hydroxy groups.

The silicone resin (i) and the silicone fluid (ii) may optionally be condensed together according to a procedure such as described in CA-A-711,756 to Pail, which patent is hereby incorporated by reference. In such a condensation reaction, the silicone resin (i) and silicone fluid (ii) are mixed together in the presence of a catalytic amount of a silanol condensation catalyst, and then the silicone resin (i) and the silicone fluid (ii) are condensed, for example, by heating under reflux conditions for 1 to 20 hours. Examples

of silanol condensation catalysts are primary, secondary and tertiary amines, carboxylic acids of these amines and quaternary ammonium salts.

Another class are those compositions described in US-A-4,591,622 and 4,584,355 to Blizzard et al., US-A-4,585,836 (Homan et al.), and US-A-4,655,767 (Woodard et al.), hereby incorporated by reference. Generally, these consist of a blend of (i) a silicone resin and (ii) a silicone fluid, which are chemically treated to reduce the silicone-bonded hydroxyl content of the blend. These may optionally be condensed, as described previously, prior to the chemical treatment.

Silicone polymeric gel forming agents should not be confused with silicone rubbers, which are not useful in these applications. Silicone polymeric gel forming agents are usually fillerless or contain low amounts (less than 5%) of fillers. By contrast, silicone rubbers typically contain about 15 to 35% filler. Fillers are generally not required in high quantities in silicone polymeric gel forming agents, because high quantities often cause the silicone polymeric gel forming agents to lose tack and adhesiveness and to increase in dynamic viscosity, making it more difficult to apply a coating of the silicone polymeric gel forming agent.

Other classes of suitable silicone polymeric gel forming agents are those described in FR-A-2 735 024 and EP-A-0 764 441, each hereby incorporated by reference.

As another alternative, the non-water soluble polymeric gel forming agents may be block copolymer thermoplastic elastomers such as ABA block copolymers such as styrene-olefin-styrene block copolymers or ethylene-propylene block copolymers. More preferably such polymers include hydrogenated grade Styrol/Ethylene-Butylene/Styrol (SEBS), Styrene/Isoprene/Styrene (SIS), and Styrol/Ethylene-Propylene/Styrol (SEPS).

Water-soluble polymeric gel forming agents

The water-soluble polymeric gel forming agents for use in the present invention are selected from synthetic or natural polymers, and mixtures thereof. In general, the pre-formed, sheet-like devices of the present invention comprise less than 50%, more

preferably less than 30% and especially less than 20% by total weight of a water-soluble polymeric gel forming agent.

Synthetic Polymers: Suitable synthetic polymers for use herein include non-ionic water-soluble polymers; acrylic acid based polymers or derivatives thereof; or cellulose derivatives; and mixtures thereof. The synthetic polymers useful herein can be categorised by their charge or constituent monomers. However, it is to be understood that the classifications herein are made for the sake of convenience and there may be overlap between the categories.

Non-Ionic Water-Soluble Polymers: Suitable non-ionic water-soluble polymers for use herein include polydimethyl acrylamide, polyvinyl pyrrolidones, polyethylene glycol monomethacrylate, poly-2-ethyl-2-oxazoline, polyvinyl alcohol, polyethylene oxide, polyvinyl ethers, copolymers of polyvinylethers and polyvinylpyrrolidone and derivatives thereof, methyl vinyl ether and maleic anhydride, copolymers of ethylene and maleic anhydride, and mixtures thereof. The uncrosslinked polymer includes repeating units derived from vinyl alcohols, vinyl ethers and their copolymers, carboxy vinyl monomer, vinyl ester monomers, esters of carboxy vinyl monomers, vinyl amide monomers, hydroxy vinyl monomers, cationic vinyl monomers containing amines or quaternary groups, N-vinyl lactam monomer and sulphonated polymers such as acrylamide sulphonated polymers and mixtures thereof. Alternatively, the uncrosslinked polymer may be a homopolymer or copolymer of a polyvinyl ether, or a copolymer derived from half ester of maleic ester. Similarly any other compatible polymer monomer units may be used as copolymers such as, for example, polyvinyl alcohol and polyacrylic acid or ethylene and vinyl acetate.

Acrylic Acid Based Polymers or Derivatives thereof: Suitable acrylic acid based polymers or derivatives thereof include polymers of acrylic acid, hydroxyethylmethacrylate, methoxydiethoxyethyl methacrylate, and hydroxydiethoxyethyl methacrylate; salts of polyacrylic acids such as ammonium polyacrylate and sodium polyacrylate; polymers of 2-acrylamido-2-methylpropanesulphonic acid or its salts (AMPS); copolymers of acrylamide and N,N'-methylene bisacrylamide; and polyacrylamide, or mixtures thereof.

Further suitable polymers for use herein include copolymers based on 2-hydroxyethylmethacrylate ("HEMA") which include the copolymer of "HEMA" and one or more co-monomers as described in US-A-5,804,107 at column 14, lines 36-67 and column 15, lines 1-34; incorporated herein by reference.

Cellulose Derivatives: Examples of cellulose derivatives suitable for use herein include carboxymethyl hydroxyethylcellulose, carboxymethyl cellulose, carboxymethylcellulose sodium, cellulose acetate propionate carboxylate, hydroxyethylcellulose, hydroxyethyl ethylcellulose, hydroxypropylcellulose, methyl cellulose, methylcellulose sodium, hydroxypropyl methylcellulose, methyl hydroxyethylcellulose, microcrystalline cellulose, sodium cellulose sulfate, and mixtures thereof. Also useful herein are the alkyl substituted celluloses. In these polymers, the hydroxy groups of the cellulose polymer is hydroyxalkylated (preferably hydroxyethylated or hydroxypropylated) to form a hydroxyalkylated cellulose which is then further modified with a $C_{10}$-$C_{30}$ straight chain or branched chain alkyl group through an ether linkage. Typically these polymers are ethers of $C_{10}$-$C_{30}$ straight or branched chain alcohols with hydroxyalkylcelluloses. Examples of alkyl groups useful herein include those selected from the group consisting of stearyl, isostearyl, lauryl, myristyl, cetyl, isocetyl, cocoyl (i.e. alkyl groups derived from the alcohols of coconut oil), palmityl, oleyl, linoleyl, linolenyl, ricinoleyl, behenyl, and mixtures thereof. Preferred among the alkyl hydroxyalkyl cellulose ethers is the material given the CTFA designation cetyl hydroxyethylcellulose, which is the ether of cetyl alcohol and hydroxyethylcellulose. This material is sold under the tradename Natrosol® CS Plus from Aqualon Corporation.

Natural Polymers: Suitable natural polymers for use herein include gelatin, polysaccharides, and mixtures thereof. Polysaccharides for use herein are preferably selected from red seaweed polysaccharides; glucomannans; galactomannans; fermentation polysaccharides, or derivatives thereof; brown seaweed polysaccharides; extracts of marine invertebrates; starch, or derivatives thereof; natural fruit extracts; plant fiber derivatives; kelp; natural plant exudates; resinous gums; and mixtures thereof. When the devices herein contain one or more polysaccharides as the water-soluble polymeric gel

forming agent(s), the devices comprise less than 10%, preferably less than 5% and more preferably less than 3% by total dry weight of a polysaccharide or mixtures thereof.

Gelatin: When gelatin is used in the devices herein, a high-molecular weight gelatin is combined with a low-molecular weight one to control the solubility. A gelatin having a low molecular weight of 20,000 or less is poor in gelling ability.

Brown Seaweed Polysaccharides: Polysaccharides which are classified as brown seaweed polysaccharides are isolated by extraction from various species of *Phaebophyceae*. Suitable brown seaweed polysaccharides for use herein include algin, alginic acid, ammonium alginate, calcium alginate, potassium alginate, sodium alginate, propylene glycol alginate, and mixtures thereof.

Red Seaweed Polysaccharides: Polysaccharides which are classified as red seaweed polysaccharides are isolated from marine plant species belonging to the class of *Rhodophyceae*. Red seaweed polysaccharides provide mechanical strength to an aqueous gel. Suitable red seaweed polysaccharides for use in the present invention include agar known in the industry under the (CTFA) trade designation as agar agar flake derived from various *Gelidium* plant species or closely related red algae commercially available as "Agar Agar 100" or "Agar Agar 150" from TIC Gums (Belcamp, MD, USA) or "Agar Agar K-100" from Gumix International Inc. (Fort Lee, NJ, USA); agarose commercially available as "Sea Plaque®" from FMC (Philadelphia, PA, USA) and "Agarose Type 1-b" from Sigma - Aldrich Co. Ltd. (Poole, UK); carrageenan, comprising the fractions lambda-, iota- and kappa- which are the water extracts obtained from various members of the *Gigartinaceae* or *Solieriaceae* families, known in the industry under the (CTFA) trade designation as chondrus, commercially available as "Gelcarin® LA", "Seakem® 3/LCM", or "Viscarin® XLV", all from FMC (Philadelphia, PA, USA); and furcellaran available from Gum Technology Corporation (Tucson, Arizona, USA) and Continental Colloids Inc. (Chicago, IL, USA), or mixtures thereof. Preferably, the red seaweed polysaccharide for use herein is selected from agar, agarose, kappa-carrageenan and furcellaran, or mixtures thereof.

Glucomannan: Glucomannans are polysaccharides which comprise an essentially linear backbone of glucose and mannose residues. Glucomannans have short side branches attached to the linear backbone and acetyl groups are randomly present at the C-6 position of a sugar unit. The acetyl groups are generally found on one per six sugar units to one per twenty sugar units. Suitable glucomannans or derivatives thereof for use herein have a ratio of mannose to glucose of from about 0.2 to about 3. Preferred glucomannans for use herein include konjac mannan, which is the generic name for the flour formed from grinding the tuber root of the Amorphophallus konjac plant (elephant yam), commercially available under the trade name "Nutricol® konjac flour" from FMC (Philadelphia, PA, USA); and deacetylated konjac mannan; or mixtures thereof.

Galactomannan: Galactomannans are vegetable reserve polysaccharides which occur in the endosperm cells of numerous seeds of *Leguminosae*. The collective term "galacto-mannan" comprises all polysaccharides which are built up of galactose and mannose residues. Galactomannans comprise a linear backbone of (1,4)-linked ß-D-manno-pyranosyl units. To these rings are attached as branches, isolated galactopyranose residues by a-(1,6)-glucoside bonds. Galactomannans may in addition also contain minor amounts of other sugar residues. Suitable galactomannans for use herein are fenugreek gum; lucern; clover; locust bean gum known for example in the industry under the (CTFA) trade designation as carob bean gum, available as "Seagul L" from FMC (Philadelphia, PA, USA); tara gum available from Starlight Products (Rouen, France) or Bunge Foods (Atlanta, GA, USA); guar gum derived from the ground endosperms of *Cyamopsis tetragonolobus*, available as "Burtonite V7E" from TIC Gums (Belcamp, MD, USA), "Jaguar C" from Rhone-Poulenc (Marietta, GA, USA), or "Supercol" from Aqualon (Wilmington, DE, USA); and cassia gum available from Starlight Products (Rouen, France), or mixtures thereof. Preferably, the galactomannans for use herein have an average one of every 1 to about 5 mannosyl units substituted with a (1,6)-linked-a-D-galactopyranosyl unit and are selected from guar gum, locust bean gum and cassia gum, or mixtures thereof.

Fermentation Polysaccharides or derivatives thereof: Fermentation polysaccharides are polysaccharides which are commercially produced by the fermentation of micro-organisms in a medium containing a carbon and nitrogen source, buffering agent, and trace elements. Suitable fermentation polysaccharides or derivatives thereof, for use in the present invention include gellan gum known in the industry under the (CTFA) trade designation as gum gellan, a high molecular weight hetero polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Pseudomonas elodea,* commercially available as "Kelcogel" from Kelco (San Diego, CA, USA); xanthan gum which is a high molecular weight hetero polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Xanthomonas campestris*, known in the industry under the (CTFA) trade designation as xanthan, commercially available for example as "Keltrol CG 1000/BT/F/GM/RD/SF/T/TF", from Calgon (Pittsburgh, PA, USA), or "Kelzan" from Kelco (San Diego, CA, USA); natto gum; pullulan; rhamsan gum; curdlan; succinoglycan; welan gum; dextran, commercially available as "Sephadex G-25" from Pharmacia Fine Chemicals (Piscataway, NJ, USA) and derivatives thereof; and sclerotium gum, commercially available as "Amigel" from Alban Muller International (Montreil, France), or mixtures thereof. Preferred fermentation polysaccharides or derivatives thereof are selected from gellan gum and xanthan gum, or mixtures thereof. More preferably the fermentation polysaccharide or derivative thereof is xanthan gum.

Extracts of Marine Invertebrates: Polysaccharides derived from marine invertebrates, specifically the exoskeleton of such invertebrates, consist chiefly of N-acetyl-D-glucosamine residues. Examples of such polysaccharides suitable for use herein include chitosan, available e.g. as "Marine Dew" from Ajinomoto (Teakneck, NJ, USA); and hydroxypropyl chitosan available e.g. as "HPCH Liquid" from Ichimaru Pharcos (Yamagata Gun Gifu-Pref, Japan) and derivatives; or mixtures thereof.

Starch or Derivatives thereof: Starches are polysaccharides which consist of various proportions of two glucose polymers, amylose and amylopectin. Suitable materials for use herein include starch; amylopectin; and dextrin commercially available as "Nadex 360" from National Starch (Bridgewater, NJ, USA) and derivatives; or mixtures thereof.

Natural Fruit Extracts: Examples of natural fruit extracts suitable for use herein include pectin; and arabian; or mixtures thereof.

Plant Fiber Derivatives: A suitable example of a plant fiber derivative for use herein is cellulose.

Natural Plant Exudates: Suitable polysaccharides obtained from natural plant exudates for use herein include karaya gum, tragacanth gum, arabic gum, tamarind gum, and ghatty gum, or mixtures thereof.

Resinous Gums: Examples of resinous gums suitable for use herein include shellac gum which is obtained from the resinous secretion of the insect *Laccifer (Tachardia) lacca*; damar gum; copal gum and rosin gum; or mixtures thereof.

Preferably, the pre-formed, unilamellar sheet-like devices herein comprise a mixture of water-soluble polymeric gel forming agents. The mixture is selected from one or more non-ionic water-soluble polymers; one or more acrylic acid based polymers or derivatives thereof; one or more polysaccharides; and mixtures thereof. For example, a preferred water-soluble polymeric gel forming agent mixture herein may comprise a polysaccharide and a non-ionic water-soluble polymer or, alternatively, it may comprise two polysaccharides. More preferably, the water-soluble polymeric gel forming agent is a polysaccharide mixture, wherein the polysaccharide mixture comprises (1) at least one red seaweed polysaccharide; brown seaweed polysaccharide; or mixtures thereof; and (2) at least one fermentation polysaccharide; galactomannan; glucomannan; natural plant exudate; or natural fruit extract; and derivatives or mixtures thereof. Even more preferably, the water-soluble polymeric gel forming agent of the devices of the present invention is a polysaccharide mixture comprising (1) at least one red seaweed polysaccharide; and (2) at least one fermentation polysaccharide; glucomannan; or galactomannan; and derivatives or mixtures thereof.

In a preferred embodiment, the water-soluble polymeric gel forming agent of the present invention is a polysaccharide mixture, comprising a red seaweed polysaccharide and a glucomannan or a galactomannan. Without being limited by theory, it is believed that in such a polysaccharide mixture, the incorporation of a glucomannan or galactomannan

may complement the red seaweed polysaccharide, and contribute to the mechanical strength of the pre-formed, unilamellar sheet-like devices of the present invention. Further, from the viewpoint of providing improved mechanical properties and preferably, a low level of syneresis from a pre-formed, unilamellar sheet-like device, preferably, the ratio of red seaweed polysaccharide to glucomannan or galactomannan in the polysaccharide mixture is from about 20:1 to about 1:5 and more preferably from about 5:1 to about 1:2.

When the polymeric gel forming agents are natural in origin, all such gels undergo syneresis, as herein before defined, to some degree. Syneresis provides one mechanism for the delivery of a benefit agent to a target area. The liquid layer exuded onto the surface of the coherent gel phase is readily available for diffusion, facilitating a short wear time of the device. The pre-formed, unilamellar sheet-like devices of the present invention desirably display a low level of syneresis and preferably, the devices herein are moist to the touch. An excessive amount of syneresis results in an ineffective and unattractive product.

The present inventors have also found that, in order to attain a polysaccharide gel with desirable mechanical properties of strength and flexibility when polysaccharide polymeric gel forming agents selected for their strength are combined with agents imparting a plasticising effect, the total level of polysaccharide polymeric gel forming agents should be kept as low as possible without compromising on mechanical strength and flexibility. It is believed that low total polysaccharide levels impart an open gel structure such that the other components of the original gel are not as tightly bound within the gel network and are freely available for diffusion.

The pre-formed, unilamellar sheet-like devices of the present invention preferably display a low level of syneresis and are moist to the touch. As aforementioned, while a device comprising a gel will always undergo some syneresis, an excessive amount of syneresis results in an ineffective and unattractive product.

Water

In a preferred embodiment of the present invention in which the at least one polymeric gel forming agent is water-soluble, the pre-formed, unilamellar sheet-like devices of the present invention include water. The total water content, if present, of a pre-formed, unilamellar sheet-like device of the present invention is from about 20% to about 99.5%, preferably from about 30% to about 95%, more preferably from about 40% to about 85% by weight of the device.

Substrate

The pre-formed, unilamellar sheet-like devices of the present invention are self-supporting and do not require supporting or strengthening by an occlusive or non-occlusive backing material often referred to as a substrate. However, a substrate, if present, may be combined with a unilamellar sheet-like device and would confer further support or strengthening. Preferably the substrate is non-occlusive. In addition, a substrate is particularly useful when the device according to the present invention has a large surface area. If the substrate is to be used to confer further support or strengthening, the substrate will be sufficiently compatible with the device of the present invention, so as not to delaminate therefrom.

A wide variety of materials can be used as the substrate. The following characteristics are desirable: (i) sufficient wet strength for use, (ii) sufficient flexibility, (iii) sufficient loft and porosity, (iv) sufficient hydrophilicity such that the gel mixture may diffuse and infiltrate into the substrate, (v) sufficient compatibility with the mixture to prevent de-lamination, (vi) sufficient transparency or translucency, and (vii) appropriate size.

Alternatively, the substrate may be used as a texturing surface. If the substrate is to be used as a texturing surface, the substrate will, preferably, delaminate easily from the device.

Examples of suitable substrates meeting one or more of the above criteria and useful herein include woven and nonwoven materials; polymeric sheet materials such as formed films; and paper substrates.

Benefit Agents

As an essential component of the present invention, the pre-formed, unilamellar sheet-like devices herein comprise a safe and effective amount of at least one benefit agent. The term "benefit agent" as used herein, means an active ingredient which provides a cosmetic and/or therapeutic effect to the area of application. Included in this definition of benefit agents are the categories listed below as well as, for example, vitamins, and humectants.

The term "safe and effective amount" as used herein, means an amount of a benefit agent high enough to modify the condition to be treated or to deliver the desired skin, hair or nail benefit, but low enough to avoid serious side effects, at a reasonable benefit to risk ratio within the scope of sound medical judgement. What is a safe and effective amount of the benefit agent will vary with the specific agent, the ability of the agent to penetrate through the skin or into, or onto the hair and/or nails, the user's age, the user's health condition, the condition of the skin, hair or nails of the user, and other like factors.

The benefit agents include their pharmaceutically-acceptable salts and by "pharmaceutically-acceptable salts" are meant any of the commonly-used salts that are suitable for use in contact with the tissues of humans without undue toxicity, irritation, incompatibility, instability, irritation, allergic response, and the like.

In general, the pre-formed, unilamellar sheet-like devices of the present invention comprise from about 0.01% to about 60%, preferably from about 0.05% to about 30% and most preferably from about 0.1% to about 20% by weight of the device of at least one benefit agent, or mixtures thereof.

The benefit agents useful herein can be categorised by their cosmetic or therapeutic benefit or their postulated mode of action. However, it is to be understood that the benefit agents useful herein can in some instances provide more than one cosmetic or therapeutic benefit or operate via more than one mode of action. Therefore, classifications herein are made for the sake of convenience and are not intended to limit the benefit agent to that particular application or applications listed. The following benefit agents are useful in the pre-formed, unilamellar sheet-like devices of the present invention.

Anti-Acne Actives: Anti-acne actives can be effective in treating and preventing *acne vulgaris*, a chronic disorder of the pilosebaceous follicles. The condition involves inflammation of the pilosebaceous apparatus thereby resulting in lesions, which may include papules, pustules, cysts, comedones, and severe scarring. The bacteria *Corynebacterium acnes* and *Staphylococcus epidermis* are usually present in the pustular contents. Examples of useful anti-acne actives include the keratolytics described in WO98/18444 incorporated herein by reference. Further useful actives include retinoids such as retinoic acid (e.g., cis and/or trans) and its derivatives (e.g., esters); retinol and its esters (e.g., retinyl propionate, retinyl acetate); abietic acid, adapalene, tazarotene, allantoin, aloe extracts, arbietic acid and its salts, ASEBIOL (from Laboratories Serobiologiques, Somerville, NJ), azaleic acid, barberry extracts, bearberry extracts, belamcanda chinensis, benzoquinolinones, benzoyl peroxide, berberine, BIODERMINE (from Sederma, Brooklyn, NY), bioflavonoids as a class, bisabolol, s-carboxymethyl cysteine, carrot extracts, cassin oil, clove extracts, citral, citronellal, climazole, COMPLETECH MBAC-OS (from Lipo, Paterson, NJ), CREMOGEN M82 (from Dragoco, Totowa, NJ), cucumber extracts, dehydroacetic acid and its salts, dehydroepi-androsterone and its sulfate derivative, dichlorophenyl imidazoldioxolan, d,l-valine and its esters, DMDM hydantoin, erythromycin, escinol, ethyl hexyl monoglyceryl ether, ethyl 2-hydroxy undecanoate, farnesol, farnesyl acetate, geraniol, geranyl geraniol, glabridin, gluconic acid, gluconolactone, glyceryl monocaprate, glycolic acid, grapefruit seed extract, gugu lipid, HEDERAGENIN (from Maruzen, Morristown, NJ), hesperitin, hinokitol, hops extract, hydrogenated rosin, 10 hydroxy decanoic acid, ichthyol, interleukin 1 alpha antagonists, KAPILARINE (from Greentech, Saint Beauzire, France), ketoconazole, lactic acid, lemon grass oil, LOCHOCHALCONE LR15 (from Maruzen, Morristown, NJ), linoleic acid, LIPACIDE C8CO (from Seppic, Paris, France), lovastatin, 4 methoxysalicylic acid, metronidazole, minocycline, mukurossi, neem seed oil, niacinamide, nicotinic acid and its esters, nisin, panthenol, 1-pentadecanol, peonia extract, peppermint extract, phelladendron extract, 2-phenyl-benzothiophene derivatives, phloretin, PHLOROGINE (from Secma, Pontrieux, France), phosphatidyl choline, proteolytic enzymes, quercetin, red sandalwood extract, rosemary extract, rutin, sage

extract, salicin, salicylic acid, serine, skull cap extract, siber hegner extract, siberian saxifrage extract, silicol, sodium lauryl sulfate, sodium sulfoacetamide, SOPHORA EXTRACT (from Maruzen, Morristown, NJ), sorbic acid, sulfur, sunder vati extract, tea tree oil, tetra hydroabietic acid, threonine, thyme extract, tioxolone, tocopherol and its esters, trehalose 6-undecylenoate, 3 tridecene-2-ol, triclosan, tropolone, UNITRIENOL T27 (from Unichem, Chicago, IL), vitamin $D_3$ and its analogs, white thyme oil, willow bark extract, wogonin, ylang ylang, zinc glycerolate, zinc linoleate, zinc oxide, zinc pyrithione, zinc sulfate, zwitterionic surfactants (e.g. cetyl dimethyl betaine) and mixtures thereof.

Emollients: Examples of emollients useful herein include mineral oil, petrolatum, $C_7$-$C_{40}$ branched chain hydrocarbons, $C_1$-$C_{30}$ alcohol esters of $C_1$-$C_{30}$ carboxylic acids, $C_1$-$C_{30}$ alcohol esters of $C_2$-$C_{30}$ dicarboxylic acids, monoglycerides of $C_1$-$C_{30}$ carboxylic acids, diglycerides of $C_1$-$C_{30}$ carboxylic acids, triglycerides of $C_1$-$C_{30}$ carboxylic acids, ethylene glycol monoesters of $C_1$-$C_{30}$ carboxylic acids, ethylene glycol diesters of $C_1$-$C_{30}$ carboxylic acids, propylene glycol monoesters of $C_1$-$C_{30}$ carboxylic acids, propylene glycol diesters of $C_1$-$C_{30}$ carboxylic acids, $C_1$-$C_{30}$ carboxylic acid monoesters and polyesters of sugars, for example, sefa cottonate (sucrose polycottonseedate), polydialkylsiloxanes, polydiarylsiloxanes, polyalkarylsiloxanes, cyclomethicones having 3 to 9 silicon atoms, vegetable oils, hydrogenated vegetable oils, polypropylene glycol $C_4$-$C_{20}$ alkyl ethers, di $C_8$-$C_{30}$ alkyl ethers, and mixtures thereof. These agents are described in more detail in WO98/18444, which is incorporated herein by reference.

Non-Steroidal Anti-Inflammatory Actives (NSAIDS): Examples of suitable NSAIDS and their esters for use herein are described in WO98/18444, incorporated herein by reference. Further non-limiting examples of non-steroidal anti-inflammatory drugs (NSAIDS) include flufenamic acid; panthenol and ether and ester derivatives thereof e.g. panthenol ethyl ether, panthenyl triacetate; pantothenic acid and salt and ester derivatives thereof, especially calcium pantothenate; aloe vera, bisabolol, allantoin and compounds of the liquorice (the plant genus/species Glycyrrhiza glabra) family, including glycyrrhetic acid,

glycyrrhizic acid, and derivatives thereof e.g. salts such as ammonium glycyrrhizinate and esters such as stearyl glycyrrhetinate.

Topical Anaesthetics: Examples of suitable topical anaesthetic drugs for use herein are benzocaine and bupivacaine. Further suitable examples are described in WO98/18444, incorporated herein by reference.

Artificial Tanning Agents and Accelerators: Artificial tanning agents can help in simulating a natural suntan by increasing melanin in the skin or by producing the appearance of increased melanin in the skin. Non-limiting examples of artificial tanning agents and accelerators include glucose tyrosinate and acetyl tyrosine, brazilin, caffeine, coffee extracts, DNA fragments, isobutyl methyl xanthine, methyl xanthine, PHOTOTAN (from Laboratoires Serobiologiques, Somerville, NJ), prostaglandins, tea extracts, theophylline, UNIPERTAN P2002 and UNIPERTAN P27 (from Unichem, Chicago, IL); and mixtures thereof. Further useful artificial tanning agents herein are described in WO98/18444 incorporated herein by reference.

Antiseptics: Examples of suitable antiseptics for use herein include alcohols, benzoate, sorbic acid, and mixtures thereof.

Anti-microbial and Anti-fungal Actives: Anti-microbial and anti-fungal actives can be effective to prevent the proliferation and growth of bacteria and fungi. Non-limiting examples of antimicrobial and antifungal actives include ketoconazole, ciclopirox, benzoyl peroxide, tetracycline, azelaic acid and its derivatives, ethyl acetate, alantolactone, isoalantolactone, alkanet extract (alaninin), anise, arnica extract (helenalin acetate and 11, 13 dihydrohelenalin), aspidium extract (phloro, lucinol containing extract), barberry extract (berberine chloride), bay sweet extract, bayberry bark extract (myricitrin), benzalkonium chloride, benzethonium chloride, benzoic acid and its salts, benzoin, benzyl alcohol, blessed thistle, bletilla tuber, bloodroot, bois de rose oil, burdock, butyl paraben, cade oil, CAE (from Ajinomoto, Teaneck, NJ), cajeput oil, cangzhu, caraway oil, cascarilla bark (sold under the trade name ESSENTIAL OIL), cedarleaf oil, chamomille, chaparral, chlorophenesin, chlorxylenol, cinnamon oil, citronella oil, clove oil, dehydroacetic acid and its salts, dill seed oil, DOWICIL 200

(from Dow Chemical, Midland, MI), echinacea, elenolic acid, epimedium, ethyl paraben, FO-TI, galbanum, garden burnet, GERMALL 115 and GERMALL II (from ISP-Sutton Labs, Wayne, NJ), german chamomile oil, giant knotweed, GLYDANT and GLYDANT PLUS (from Lonza, Fairlawn, NJ), grapefruit seed oil, hexamidine diisethionate, hinokitiol, honey, honeysuckle flower, hops, immortelle, iodopropynl butyl carbamide (available from Lonza, Fairlawn, NJ), isobutyl paraben, isopropyl paraben, JM ACTICARE (from Microbial Systems International, Nottingham, UK), juniper berries, KATHON CG (from Rohm and Haas, Philadelphia, PA, USA), labdanum, lavender, lemon balm oil, lemon grass, methyl paraben, mint, mume, mustard, myrrh, neem seed oil, ortho phenyl phenol, OLIVE LEAF EXTRACT (from Bio Botanica, Hauppauge, NY), parsley, patchouli oil, peony root, PHENONIP (from Nipa Labs, Wilmington, DE), phytosphingosine, pine needle oil, PLANSERVATIVE (from Campo Research, Raffles Quay, Singapore), propyl paraben, purslane, quillaira, rhubarb, rose geranium oil, rosemary, sage, salicylic acid, sassafras, savory, sichuan lovage, sodium meta bisulfite, sodium sulfite, SOPHOLIANCE (from Soliance, Compiegne, France), sorbic acid and its salts, sphingosine, stevia, storax, tannic acid, tea, tea tree oil (cajeput oil), thyme, triclosan, triclocarban, tropolone, turpentine, umbelliferone (antifungal), and yucca, or mixtures thereof. Further examples of anti-microbial and antifungal actives useful herein are described in WO98/18444 incorporated herein by reference.

Skin Soothing Agents: Skin soothing agents can be effective in preventing or treating inflammation of the skin. The soothing agent enhances the skin appearance benefits of the present invention, e.g., such agents contribute to a more uniform and acceptable skin tone or colour. Non-limiting examples of skin soothing agents include absinthium, acacia, aescin, alder buckthorn extract, allantoin, aloe, APT (from Centerchem, Stamford, CT), arnica, astragalus, astragalus root extract, azulene, BAICALIN SR 15 (from Barnet Products Dist., Englewood, NJ), baikal skullcap, baizhu, balsam canada, bee pollen, BIOPHYTEX (from Laboratories Serobiologiques, Somerville, NJ), bisabolol, black cohosh, black cohosh extract, blue cohosh, blue cohosh extract, boneset, borage, borage oil, borage seed oil, bromelain, calendula, calendula extract, CANADIAN WILLOWBARK EXTRACT (from Fytokem), candelilla wax, cangzhu, canola

phytosterols, capsicum, carboxypeptidase, celery seed, celery stem extract, CENTAURIUM (from Sederma, Brooklyn, NY), centaury extract, chamazulene, chamomile, chamomile extract, chaparral, chaste tree, chaste tree extract, chickweed, chicory root, chicory root extract, chirata, chishao, collodial oatmeal, comfrey, comfrey extract, CROMIST CM GLUCAN (from Croda, Parsippany, NJ), darutoside, dehurian angelica, DEVIL'S CLAW (from MMP Plainfield, NJ), divalent metals (such as magnesium, strontium, manganese), doggrass, dogwood, EASHAVE (from Pentapharm, Basel, Switzerland), eleuthero, ELHIBIN (from Pentapharm, Basel, Switzerland), ENTELINE 2 (from Secma, Pontrieux, France), ephedra, epimedium, esculoside, evening primrose, eyebright, EXTRACT LE-100 (from Sino Lion, World Trade Centre, NY), fangfeng, feverfew, ficin, forsythia fruit, ganoderma, gaoben, GATULINE A (from Gattefosse, Saint Priest, France), gentian, germanium extract, gingko bilboa, ginkgo, ginseng extract, goldenseal, gorgonian extract, gotu kola, grape fruit extract, guaiac wood oil, guggal extract, helenalin esters, henna, honeysuckle flower, horehound extract, horsechestnut, horsetail, huzhang, hypericum, ichthyol, immortelle, ipecac, job's tears, jujube, kola extract, LANACHRYS 28 (from Lana Tech, Paris, France), lemon oil, lianqiao, licorice root, ligusticum, ligustrum, lovage root, luffa, mace, magnolia flower, manjistha extract, margaspidin, margaspidin, matricin, MICROAT IRC (from Nurture, Missoula, MT) mints, mistletoe, MODULENE (from Seporga, Sophia Antipolis, France), mung bean extract, musk, oat extract, orange, panthenol, papain, peony bark, peony root, PHYTOPLENOLIN (from Bio Botanica, Hauppauge, NY), PREREGEN (from Pentapharm, Basel, Switzerland), purslane, QUENCH T (from Centerchem, Stamford, CT), quillaia, red sage, rehmannia, rhubarb, rosemary, rosmarinic acid, royal jelly, rue, rutin, sandalwood, sanqi, sarsaparilla, saw palmetto, SENSILINE (from Silab, Brive, France), SIEGESBECKIA (from Sederma, Brooklyn, NY), stearyl glycyrrhetinate, STIMUTEX (from Pentapharm, Basel, Switzerland), storax, sweet birch oil, sweet woodruff, tagetes, tea extract, thyme extract, tienchi ginseng, tocopherol, tocopheryl acetate, triclosan, turmeric, urimei, ursolic acid, white pine bark, witch hazel, xinyi, yarrow, yeast extract, yucca, and mixtures thereof.

Sunscreening Agents: Examples of suitable sunscreening agents useful herein are described in WO98/18444, incorporated herein by reference. Further examples of sunscreens which are useful herein include diethanolamine p-methoxycinnamate, dioxybenzone, ethyl dihydroxypropyl PABA, glyceryl aminobenzoate, lawsome and dihydroxyacetone, menthyl anthranilate, methyl anthranilate, octyl dimethyl PABA, red petroleum, sulisobenzone, triethanolamine salicylate, and mixtures thereof.

Skin Barrier Repair Aids: Skin barrier repair actives are those skin care actives which can help repair and replenish the natural moisture barrier function of the epidermis. Non-limiting examples of skin barrier repair aids include brassicasterol, caffeine, campesterol, canola derived sterols, CERAMAX (from Quest, Ashford, England), CERAMIDE HO3TM (from Sederma, Brooklyn, NY), CERAMIDE II and CERAMIDE III (from Quest, Ashford, England), CERAMIDE IIIB (available from Cosmoferm, Delft, Netherlands), CERAMIDE IS 3773 (from Laboratories Serobiologiques, Somerville, NJ), CERAMINOL (from Inocosm, Chatenay Malabry, France), CERASOL and CEPHALIP (from Pentapharm, Basel, Switzerland), cholesterol, cholesterol hydroxystearate, cholesterol isostearate, 7-dehydrocholesterol, DERMATEIN BRC and DERMATEIN GSL (from Hormel, Austin, MN), ELDEW CL 301 (from Ajinomoto, Teaneck, NJ), ELDEW PS 203 (from Ajinomoto, Teaneck, NJ), FITROBROSIDE (from Pentapharm, Basel, Switzerland), GENEROL 122 (from Henkel, Hoboken, NJ), glyceryl serine amide, lactic acid, LACTOMIDE (from Pentapharm, Basel, Switzerland), lanolin, lanolin alcohols, lanosterol, lauric acid n laurylglucamide, lipoic acid, n-acetyl cysteine, serine, n-acetyl-L-serine, n-methyl-L-serine, NET STEROL-ISO (from Barnet Products, Englewood, NJ), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, palmitic acid, panthenol, panthetine, phosphodiesterase inhibitors, PHYTO/CER (from Intergen, Purchaser, NY), PHYTOGLYCOLIPID MILLET EXTRACT (from Barnet Products Distributor, Englewood, NJ), PHYTOSPHINGOSINE (from Gist Brocades, King of Prussia, PA), PSENDOFILAGGRIN (from Brooks Industries, South Plainfield, NJ), QUESTAMIDE H (from Quest, Ashford, England), serine, stigmasterol, sitosterol, stigmastanol, soybean derived sterols, sphingosine, s-lactoyl glutathione, stearic acid, SUPER STEROL ESTERS (from Croda, Parsippany, NJ), thioctic acid, THSC

CERAMIDE OIL (from Campo Research, Raffles Quay, Singapore), trimethyl glycine, tocopheryl nicotinate, vitamin D3 and analogs or derivatives thereof, and Y2 (from Ocean Pharmaceutical), or mixtures thereof.

Anti-Wrinkle and Anti-Skin Atrophy Actives: Anti-wrinkle and anti-skin atrophy actives can be effective in replenishing or rejuvenating the epidermal and/or dermal layer. These actives generally provide these desirable skin care benefits by promoting or maintaining the natural process of desquamation and/or building skin matrix components (e.g., collagen and glycosaminoglycans). Non-limiting examples of antiwrinkle and anti-skin atrophy actives include nicotinic acid and its esters, nicotinyl alcohol, estrogens and estrogenic compounds, or mixtures thereof. Further suitable antiwrinkle and anti-skin atrophy actives useful herein are described in WO98/18444 incorporated herein by reference.

Skin Repair Actives: Skin repair actives can be effective in repairing the epidermal and/or dermal layer. Non-limiting examples of skin repair actives include actein 27 - deoxyactein cimicifugoside (cimigoside), adapalene, tazarotene, ademethionine, adenosine, aletris extract, aloe derived lectins, 3-aminopropyl dihydrogen phosphate, AMADORINE (from Barnet Products, Englewood, NJ), anise extracts, AOSINE (from Secma, Pontrieux, France), arginine amino benzoate, ASC III (from E. Merck, Darmstadt, Germany), ascorbic acid and derivatives thereof, ascorbyl palmitate, asiatic acid, asiaticosides, ARLAMOL GEO (from ICI, Wilmington, DE), azaleic acid, benzoic acid derivatives, bertholletia extracts, betulinic acid, BIOCHANIN A, BIOPEPTIDE CL and BIOPEPTIDE EL (from Sederma, Brooklyn, NY), biotin, blackberry bark extract, blackberry lily extracts, black cohosh extract, blue cohosh extract, butanoyl betulinic acid, catecholamines, chalcones, chaste tree extract, cis retinoic acid, citric acid esters, clover extracts, coenzyme Q10 (ubiquinone), coumestrol, CPC PEPTIDE (Barnet Products, located in Englewood, NJ), daidzein, dang gui extract, darutoside, debromo laurinterol, 1-decanoyl-glycero-phosphonic acid, dehydrocholesterol, dehydrodicreosol, dehydrodieugenol, dehydroepiandrosterone, DERMOLECTINE (from Sederma, Brooklyn, NY), dehydroascorbic acid and derivatives thereof, dehydroepiandrosterone

sulfate, dianethole, 2,4-dihydroxybenzoic acid, diosgenin, disodium ascorbyl phosphate, dodecanedioic acid, EDERLINE (from Seporga, Sophia Antipolis, France), ELESERYL SH (from Laboratories Serobiologiques, Somerville, NJ), ENDONUCLEINE (from Laboratories Serobiologiques, Somerville, NJ), equol, ergosterol, eriodictyol, estrogen and its derivatives, ethocyn, eythrobic acid, farnesol, farnesyl acetate, fennel extract, FIBRASTIL (from Sederma, Brooklyn, NY), FIBROSTIMULINES S AND P (from Sederma, Brooklyn, NY), FIRMOGEN IS 8445 (from Laboratories Serobiologiques, Somerville, NJ), flavonoids (especially flavanones such as unsubstituted flavanone and chalcones such as unsubstituted chalcone and monohydroxy and dihydroxy chalcones), formononetin, forsythia fruit extract, gallic acid esters, gamma amino butyric acid, GATULINE RC (from Gattlefosse, Saint Priest, France), genistein, genisteine, genistic acid, gentisyl alcohol, gingko bilboa extracts, ginseng extracts, ginsenoside, $R_O$, $R_{6-1}$, $R_{6-2}$, $R_{6-3}$, $R_C$, $R_D$, $R_E$, $R_F$, $R_{F-2}$, $R_{G-1}$, $R_{G-2}$, gluco pyranosyl-l-ascorbate, glutathione and its esters, glycitein, eptyloxy 4 salicylic acid, hesperitin, hexahydro curcumin, hmg-coenzyme A reductase inhibitors, hops extracts, 11 hydroxy undecanoic acid, 10 hydroxy decanoic acid, 25-hydroxycholesterol, ISOFAVONE SG 10 (from Barnet Products, Englewood, NJ), kinetin, l-2-oxo-thiazolidine-4-carboxylic acid esters, lactate dehydrogenase inhibitors, 1-lauryl,-lyso-phosphatidyl choline, lectins, LICHOCHALCONE LR15 (from Maruzen, Morristown, NJ), licorice extracts, lipoic acid, lumisterol, luteolin, magnesium ascorbyl phosphate, melatonin, melibiose, metalloproteinase inhibitors, methoprene, methoprenic acid, 4-methoxy salicylic acid, mevalonic acid, MPC COMPLEX (from CLR, Berlin, Germany), N-acetyl cysteine, N-methyl serine, N-methyl taurine, N,N'-bis (lactyl) cysteamine, naringenin, neotigogenin, 5-octanoyl salicylic acid, O- desmethylangoiensin, oleanolic acid, pantethine, phenylalanine, photoanethone, phytic acid and its salts, piperidine, placental extracts, pratensein, pregnenolone, pregnenolone acetate, pregnenolone succinate, premarin, quillaic acid, raloxifene, REPAIR FACTOR 1 (from Sederma, Brooklyn, NY), REPAIR FACTOR SPC (from Sederma, Brooklyn, NY), retinal, retinoates (esters of $C_2$-$C_{20}$ alcohols), retinol, retinyl acetate, retinyl glucuronate, retinyl linoleate, retinyl palmitate, retinyl propionate, REVITALIN BT (from Pentapharm, Basel, Switzerland), s-

carboxymethyl cysteine, salicylic acid, SEANAMINE FP (from Laboratories Serobiologiques, Somerville, NJ), sodium ascorbyl phosphate, soya extracts, spleen extracts, tachysterol, taurine, tazarotene, thymulen, thymus extracts, thyroid hormones, tigogenin, tocopheryl retinoate, toxifolin, trans retinoic acid, traumatic acid, tricholine citrate, trifoside, uracil derivatives, ursolic acid, vitamin $D_3$ and its analogs, vitamin K, vitex extract, yam extract, yamogenin, and zeatin, or mixtures thereof.

Lipids: Examples of suitable lipids include cetyl ricinoleate, cholesterol hydroxystearate, cholesterol isostearate, CREMEROL (from Amerchol, Edison, NJ), ELDEW C1301 (from Ajinomoto, Teaneck, NJ), lanolin, MODULAN (from Amerchol, Edison, NJ), OHLAN (from Amerchol, Edison, NJ), petrolatum, phytantriol, and SUPER STEROL ESTERS (from Croda, Parsippany, NJ), or mixtures thereof.

Skin Lightening Agents: Skin lightening agents can actually decrease the amount of melanin in the skin or provide such an effect by other mechanisms. Skin lightening agents suitable for use herein are described in EP-A-758,882 and EP-A-748,307, both of which are incorporated herein by reference. Further examples of skin lightening agents include adapalene, aloe extract, aminotyrosine, ammonium lactate, anethole derivatives, apple extract, arbutin, ascorbic acid and derivatives thereof, ascorbyl palmitate, azelaic acid, bamboo extract, bearberry extract, bletilla tuber, bupleurum falcatum extract, burnet extract, BURNET POWDER (from Barnet Products, Englewood, NJ), butyl hydroxy anisole, butyl hydroxy toluene, chuanxiong, dang-gui, deoxyarbutin, 1,3-diphenyl propane derivatives, 2, 5 dihydroxybenzoic acid and its derivatives, 2-(4-acetoxyphenyl)-1,3 dithane, 2-(4-hydroxyphenyl)-1,3 dithane, ellagic acid, escinol, estragole derivatives, esculoside, esculetin, FADEOUT (from Pentapharm, Basel, Switzerland), fangfeng, fennel extract, gallic acid and its derivatives, ganoderma extract, gaoben, GATULINE WHITENING (from Gattefosse, Saint Priest, France), genistic acid and its derivatives, gentisyl alcohol, glabridin and its derivatives, gluco pyranosyl-l-ascorbate, gluconic acid, glucosamine, glycolic acid, glycyrrhizinic acid, green tea extract, 4-hydroxy-5-methyl-3[2h]-furanone, hydroquinine, 4-hydroxyanisole and its derivatives, 4-hydroxy benzoic acid derivatives, hydroxycaprylic acid, inositol ascorbate, kojic acid, lactic acid, lemon

extract, licorice extract, LICORICE P-TH (from Barnet Products, Englewood, NJ), linoleic acid, magnesium ascorbyl phosphate, MELFADE (from Pentapharm, Basel, Switzerland), MELAWHITE (from Pentapharm, Basel, Switzerland), morus alba extract, mulberry root extract, niacinamide, nicotinic acid and its esters, nicotinyl alcohol, 5-octanoyl salicylic acid, parsley extract, phellinus linteus extract, placenta extract, pyrogallol derivatives, retinoic acid, retinol, retinyl esters (acetate, propionate, palmitate, linoleate), 2,4 resorcinol derivatives, 3,5 resorcinol derivatives, rose fruit extract, rucinol, salicylic acid, song-yi extract, SOPHORA POWDER (from Barnet Products, Englewood, NJ), 4-thioresorein, 3,4,5 trihydroxybenzyl derivatives, tranexamic acid, TYROSLAT 10,11 (from Fytokem), vitamin $D_3$ and its analogs, yeast extract, or mixtures thereof.

Sebum Inhibitors: Sebum inhibitors can decrease the production of sebum in the sebaceous glands. Examples of suitable sebum inhibitors include aluminium hydroxy chloride, ASEBIOL (from Laboratories Serobiologiques, Somerville, NJ), BIODERMINE (from Sederma, Brooklyn, NY), climbazole, COMPLETECH MBAC-0S (from Lipo, Peterson, NJ), corticosteroids, cucumber extracts, dehydroacetic acid and its salts, dichlorophenyl imidazoldioxolan, ketoconazole, LICHOCHALCONE LR 15 (available from Maruzen), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, phloretin, PHLOROGINE (from Secma, Pontrieux, France), pyridoxine and derivatives thereof, s-carboxylmethyl cysteine, SEPICONTROL AS, spironolactone, tioxolone, tocopherol, UNITRIENOL T27 (from Unichem, Chicago IL), and ZINCIDONE (from UCIB, Clifton, NJ), or mixtures thereof.

Sebum Stimulators: Sebum stimulators can increase the production of sebum by the sebaceous glands. Non-limiting examples of sebum stimulators include bryonolic acid, COMPLETECH MBAC-DS (from Lipo, Paterson, NJ), dehydroepiandrosterone (also known as DHEA), orizanol, and mixtures thereof.

Skin Sensates: Non-limiting examples of suitable skin sensates for use herein include agents which impart a cool feel such as camphor, thymol, 1-menthol and derivatives thereof, eucalyptus, carboxamides; menthane ethers and menthane esters; and agents imparting a warm feel such as cayenne tincture, cayenne extract, cayenne powder,

vanillylamide nonanoate, nicotinic acid derivatives (benzyl nicotinate, methyl nicotinate, phenyl nicotinate, etc.), capsaicin, nasturtium officinale extract, *Zanthoxylum piperitum* extract and ginger extract, or mixtures thereof.

Protease Inhibitors: Protease inhibitors are compounds which inhibit the process of proteolysis, that is, the splitting of proteins into smaller peptide fractions and amino acids. Examples of suitable protease inhibitors include A E COMPLEX (from Barnet Products, Englewood, NJ), ALE (from Laboratoires Seporgia, Sophia Antipolis, France), allicin, AOSAINE (from Secma Biotechnologies Marine, Pontrieux, France), APROTININ (from Pentapharm AG, Basel, Switzerland), areca catechu extracts, BLUE ALGAE EXTRACT (from Collaborative Labs Inc., East Setauket, NY), CENTAURIUM (from Sederma, Brooklyn, NY), CMST (from Bioetica Inc., Portland, ME), DERMOPROTECTINE (from Sederma, Brooklyn, NY), DISACOSIDE HF 60 (from Barnet Products, Englewood, NJ), ELHIBIN (from Pentapharm AG, Basel, Switzerland), FLUID OUT COLLOID (from Vegetech, Glendale, CA), HYPOTAURINE (from Sogo Pharmaceutical Co. Ltd., Chiroda-ku Tokyo), IN CYTE HEATHER (from Collaborative Labs Inc., East Setauket, NY), MICROMEROL (from Collaborative Labs Inc, East Setauket, NY), PEFABLOC SP (from Pentapharm AG, Basel, Switzerland), SEPICONTROL AS (from Seppic, Paris, France), SIEGESBECKIA (from Sederma located in Brooklyn, NY), SOPHORINE and THIOTAINE (from Barnet Products, Englewood, NJ), and mixtures thereof.

Skin Tightening Agents: Examples of skin tightening agents include BIOCARE SA (from Amerchol, Edison, NJ), egg albumen, FLEXAN 130 (from National Starch, Bridgewater, NJ), GATULINE LIFTING (from Gattefosse, Saint Priest, France), PENTACARE HP (from Pentapharm AG, Basel, Switzerland), VEGESERYL (from Laboratories Serobioloques, Somerville, NJ), and mixtures thereof.

Anti-Itch Ingredients: Examples of anti-itch ingredients include STIMU-TEX (from Pentapharm AG, Basel, Switzerland), TAKANAL (from Ikeda-Distributor, Tokyo, Japan), ICHTHYOL (from International Sourcing-Distributor, Upper Saddle River, NJ), OXYGENATED GLYCERYL TRIESTERS (from Laboratoires Seporgia, Sophia Antipolis, France ), and mixtures thereof.

Agents for Inhibiting Hair Growth: Examples of suitable agents for inhibiting hair growth include 17 beta estradiol, adamantyguanidines, adamantylamidines, adenylosuccinate synthase inhibitors, anti angiogenic steroids, aspartate transcarbamylase inhibitors, betamethasone valerate, bisabolol, copper ions, curcuma extract, cycloxygenase inhibitors, cysteme pathway inhibitors, dehydroacetic acid, dehydroepiandrosterone, diopyros leak extract, epidermal growth factor, epigallocatechin, essential fatty acids, evening primrose oil, gamma glutamyl transpeptidase inhibitors, ginger oil, glucose metabolism inhibitors, glutamine metabolism inhibitors, glutathione, green tea extracts, heparin, KAPILANNE (from International Sourcing Distributor, Upper Saddle River, NJ), L-5-diaminopentanoic acid, L-aspargine synthase inhibitors, linoleic acid, lipoxygenase inhibitors, longa extract, mimosinamine dihydrochloride, mimosine, nitric oxide synthase inhibitors, non-steroidal anti-inflamatories, ornithine decarboxylase inhibitors, ornithine aminotransferase inhibitors, panthenol, phorhetur, phosphodiesterase inhibitors, pleione extract, protein kinase C inhibitors, 5-alpha reductase inhibitors, sulfhydral reactive compounds, tioxolone, transforming growth factor beta 1, urea, zinc ions, and mixtures thereof.

5-Alpha Reductase Inhibitors: Examples of 5-alpha reductase inhibitors include CLOVE 55 (from Barnet Products Distributor, Englewood, NJ), ethynylestradiol, genisteine, genistine, Licochalcone LR-15, saw palmetto extracts, SOPHORA EXTRACT (from Maruzen, Morristown, NJ), ZINCIDONE (from UCIB, Clifton, NJ), and mixtures thereof.

Desquamation Enzyme Enhancers: These agents enhance the activity of endogenous desquamating enzymes. Non-limiting examples of desquamation enzyme enhancers include N-methyl serine, serine, trimethyl glycine, and mixtures thereof.

Anti-Glycation Agents: Anti-glycation agents prevent the sugar induced crosslinking of collagen. A suitable example of an anti-glycation agent includes AMADORINE (from Barnet Products Distributor, Englewood, NJ).

Preferred examples of benefit agents useful herein include those selected from the group consisting of ascorbic acid and derivatives thereof, salicylic acid, niacinamide, tocopheryl nicotinate, benzoyl peroxide, 3-hydroxy benzoic acid, flavonoids (e.g., flavanone,

chalcone), farnesol, phytantriol, glycolic acid, lactic acid, 4-hydroxy benzoic acid, acetyl salicylic acid, 2-hydroxybutanoic acid, 2-hydroxypentanoic acid, 2-hydroxyhexanoic acid, cis-retinoic acid, trans-retinoic acid, retinol, retinyl esters (e.g., retinyl propionate), phytic acid, N-acetyl-L-cysteine, lipoic acid, tocopherol and its esters (e.g., tocopheryl acetate), azelaic acid, arachidonic acid, tetracycline, ibuprofen, naproxen, ketoprofen, hydrocortisone, acetominophen, resorcinol, phenoxyethanol, phenoxypropanol, phenoxyisopropanol, 2,4,4'-trichloro-2'-hydroxy diphenyl ether, 3,4,4'-trichloro-carbanilide, octopirox, lidocaine hydrochloride, clotrimazole, miconazole, ketoconazole, neomycin sulfate, theophylline, and mixtures thereof.

For cosmetic methods of treatment of the skin, hair or nails, the cosmetic benefit agent is preferably selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, emollients, humectants, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, lipids, sebum inhibitors, sebum stimulators, sunscreening agents, protease inhibitors, skin tightening agents, anti-itch ingredients, and desquamation enzyme enhancers, or mixtures thereof.

Humectants

Preferred pre-formed, unilamellar sheet-like devices comprise at least one humectant. Humectants can be added to achieve a plasticising effect and to increase the moisturising characteristics of the pre-formed unilamellar sheet-like device when applied to the target surface. Certain humectants such as hexylene glycol may also contribute to the antibacterial properties and characteristics of a pre-formed, unilamellar sheet-like device of the present invention. Further, without wishing to be limited by theory, it is thought that incorporating humectants into the pre-formed, sheet-like unilamellar devices of the present invention, increases the stability of the devices such that they are less likely to undergo decomposition under extreme temperature conditions. In general, the pre-formed, unilamellar sheet-like devices of the present invention comprise from about 1.0% to about 45%, preferably from about 5% to about 40%, more preferably from about 10% to about 30% by weight of a humectant.

Suitable humectants for use in the present invention are described in WO98/22085, WO98/18444 and WO97/01326, all incorporated herein by reference. Further suitable humectants include amino acids and derivatives thereof such as proline and arginine aspartate, 1,3-butylene glycol, propylene glycol and water and codium tomentosum extract, collagen amino acids or peptides, creatinine, diglycerol, biosaccharide gum-1, glucamine salts, glucuronic acid salts, glutamic acid salts, polyethylene glycol ethers of glycerin (e.g. glycereth 20), glycerin, glycerol monopropoxylate, glycogen, hexylene glycol, honey and extracts or derivatives thereof, hydrogenated starch hydrolysates, hydrolyzed mucopolysaccharides, inositol, keratin amino acids, LAREX A-200 (available from Larex), glycosaminoglycans, methoxy PEG 10, methyl gluceth-10 and 20 (both commercially available from Amerchol, Edison, NJ), methyl glucose, 3-methyl-1,3-butandiol, N-acetyl glucosamine salts, panthenol, polyethylene glycol and derivatives thereof (such as PEG 15 butanediol, PEG 4, PEG 5 pentaerythritol, PEG 6, PEG 8, PEG 9), pentaerythritol, 1,2 pentanediol, PPG-1 glyceryl ether, PPG-9, 2-pyrrolidone-5-carboxylic acid and its salts such as glyceryl PCA, saccharide isomerate, SEACARE (available from Secma), sericin, silk amino acids, sodium acetylhyaluronate, sodium hyaluronate, sodium poly-aspartate, sodium polyglutamate, sorbeth 20, sorbeth 6, sugar and sugar alcohols and derivatives thereof such as glucose, mannose and polyglycerol sorbitol, trehalose, triglycerol, trimethyolpropane, tris (hydroxymethyl) amino methane salts, and yeast extract, or mixtures thereof.

Preferably, the humectants for use herein are selected from glycerine, butylene glycol, hexylene glycol, panthenol and polyethylene glycol and derivatives thereof, or mixtures thereof.

Emulsifiers/Surfactants

The pre-formed, unilamellar sheet-like devices of the present invention can also optionally comprise one or more surfactants and/or emulsifiers. Emulsifiers and/or surfactants, generally help to disperse and suspend the discontinuous phase within the continuous phase. A surfactant may also be useful if the product is intended for skin, hair or nail cleansing. For convenience hereinafter emulsifiers will be referred to under the

term 'surfactants', thus 'surfactant(s)' will be used to refer to surface active agents whether used as emulsifiers or for other surfactant purposes such as skin, hair or nail cleansing. Known or conventional surfactants can be used in the composition, provided that the selected agent is chemically and physically compatible with essential components of the composition, and provides the desired characteristics. Suitable surfactants include silicone materials, non-silicone materials, and mixtures thereof.

The compositions of the present invention preferably comprise from about 0.01% to about 15% of a surfactant or mixture of surfactants. The exact surfactant or surfactant mixture chosen will depend upon the pH of the composition and the other components present. Preferred surfactants are nonionic.

Among the nonionic surfactants that are useful herein are the condensation products of alkylene oxides with fatty acids (i.e. alkylene oxide esters of fatty acids). These materials have the general formula $RCO(X)_nOH$ wherein R is a $C_{10-30}$ alkyl group, X is $-OCH_2CH_2-$ (i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 200. Other nonionic surfactants are the condensation products of alkylene oxides with 2 moles of fatty acids (i.e. alkylene oxide diesters of fatty acids). These materials have the general formula $RCO(X)_nOOCR$ wherein R is a $C_{10-30}$ alkyl group, X is $-OCH_2CH_2-$ or $-OCH_2CHCH_3-$, and n is an integer from about 6 to about 100. Other nonionic surfactants are the condensation products of alkylene oxides with fatty alcohols (i.e. alkylene oxide ethers of fatty alcohols). These materials have the general formula $R(X)_nOR'$ wherein R is a $C_{10-30}$ aliphatic group, X is $-OCH_2CH_2-$ or $-OCH_2CHCH_3-$, n is an integer from about 6 to about 100 and R' is H or a $C_{10-30}$ aliphatic group, examples of which include PEG 40 hydrogenated castor oil and PEG 60 hydrogenated castor oil, respectively available under the trade names "Cremophor RH 40" and "Cremophor RH 60" from BASF (Parsippany, NJ, USA); isoceteth-20, available under the trade name "Arlasolve 200" from ICI (Wilmington, MA, USA); and oleth-20, available under the trade name "Volpo N20" from Croda Chemicals Ltd. (Goole, North Humberside, England). Still

other nonionic surfactants are the condensation products of alkylene oxides with both fatty acids and fatty alcohols [i.e. wherein the polyalkylene oxide portion is esterified on one end with a fatty acid and etherified (i.e. connected via an ether linkage) on the other end with a fatty alcohol]. These materials have the general formula $RCO(X)_nOR'$ wherein R and R' are $C_{10-30}$ alkyl groups, X is $-OCH_2CH_2-$ or $-OCH_2CHCH_3-$, and n is an integer from about 6 to about 100, examples of which include ceteth-6, ceteth-10, ceteth-12, ceteareth-6, ceteareth-10, ceteareth-12, steareth-6, steareth-10, steareth-12, PEG-6 stearate, PEG-10 stearate, PEG-100 stearate, PEG-12 stearate, PEG-20 glyceryl stearate, PEG-80 glyceryl tallowate, PEG-10 glyceryl stearate, PEG-30 glyceryl cocoate, PEG-80 glyceryl cocoate, PEG-200 glyceryl tallowate, PEG-8 dilaurate, PEG-10 distearate, and mixtures thereof.

Other nonionic surfactants that are useful herein are alkyl glucosides and alkyl polyglucosides which are described in more detail in WO98/18444, incorporated herein by reference. Still other useful nonionic surfactants include polyhydroxy fatty acid amide surfactants, which are described in more detail in WO98/04241.

Other nonionic surfactants suitable for use herein include sugar esters and polyesters, alkoxylated sugar esters and polyesters, $C_1$-$C_{30}$ fatty acid esters of $C_1$-$C_{30}$ fatty alcohols, alkoxylated derivatives of $C_1$-$C_{30}$ fatty acid esters of $C_1$-$C_{30}$ fatty alcohols, alkoxylated ethers of $C_1$-$C_{30}$ fatty alcohols, polyglyceryl esters of $C_1$-$C_{30}$ fatty acids, $C_1$-$C_{30}$ esters of polyols, $C_1$-$C_{30}$ ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, and mixtures thereof. Examples of these non-silicon-containing surfactants include: polysorbate 20, polyethylene glycol 5 soya sterol, steareth-20, ceteareth-20, PPG-2 methyl glucose ether distearate, polysorbate 80; polysorbate 60, available under the trade name "Tween 60" from ICI (Wilmington, MA, USA); glyceryl stearate, sorbitan monolaurate, polyoxyethylene 4 lauryl ether sodium stearate, polyglyceryl-4 isostearate, hexyl laurate, PPG-2 methyl glucose ether distearate, and mixtures thereof.

Preferred among the nonionic surfactants are those selected from the group consisting of ceteareth-12, sucrose cocoate, steareth-100, polysorbate 60, PEG-60 Hydrogenated Castor Oil, isoceteth-20, oleth-20, PEG-100 stearate, and mixtures thereof.

Other suitable emulsifiers for use herein are polyoxypropylene, polyoxyethylene ethers of fatty alcohols. These materials have the general formula $R(CH_2CHCH_3O)_x$-$(CH_2CH_2O)_y$-H, wherein R is an $OC_{10}$-$C_{30}$ alkyl group or $C_{10}$-$C_{30}$ alkyl group, x has an average value from 1 to 20 and y has an average value from 1 to 30, examples of which include PPG-6-decyltetradeceth-30, available under the trade name "Pen 4630" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); PPG-6-Decyltetradeceth-20, available under the trade name "Pen 4620" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); and PPG-5-Ceteth-20, available under the trade name "Procetyl AWS" from Croda Chemicals Ltd. (Goole, North Humberside, England).

Another emulsifier useful herein is a fatty acid ester blend based on a mixture of sorbitan or sorbitol fatty acid ester and sucrose fatty acid ester, as described in more detail in WO98/22085, incorporated by reference herein.

The hydrophilic surfactants useful herein can alternatively or additionally include any of a wide variety of cationic, anionic, zwitterionic, and amphoteric surfactants such as are known in the art. See, e.g., McCutcheon's, Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation; US-A-5,011,681 to Ciotti et al., issued April 30, 1991; US-A-4,421,769 to Dixon et al., issued December 20, 1983; and US-A-3,755,560 to Dickert et al., issued August 28, 1973; these four references are incorporated herein by reference in their entirety.

A wide variety of cationic surfactants are useful herein. Suitable cationic surfactants for use herein are disclosed in WO98/18444, incorporated herein by reference.

A wide variety of anionic surfactants are also useful herein. See, e.g., US-A-3,929,678, to Laughlin et al., issued December 30, 1975, which is incorporated herein by reference in its entirety. Exemplary anionic surfactants include the alkoyl isethionates (e.g., $C_{12}$ - $C_{30}$), alkyl and alkyl ether sulfates and salts thereof, alkyl and alkyl ether phosphates and

salts thereof, alkyl methyl taurates (e.g., $C_{12}$ - $C_{30}$), and soaps (e.g., alkali metal salts, e.g., sodium or potassium salts) of fatty acids.

Amphoteric and zwitterionic surfactants are also useful herein. Examples of amphoteric and zwitterionic surfactants which can be used in the compositions of the present invention are those which are broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be straight or branched chain and wherein one of the aliphatic substituents contains from about 8 to about 22 carbon atoms (preferably $C_8$ - $C_{18}$) and one contains an anionic water solubilising group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Examples are alkyl imino acetates, and iminodialkanoates and aminoalkanoates, imidazolinium and ammonium derivatives. Other suitable amphoteric and zwitterionic surfactants are those selected from the group consisting of betaines, sultaines, hydroxysultaines, alkyl sarcosinates (e.g., $C_{12}$ - $C_{30}$), and alkanoyl sarcosinates.

The pre-formed, unilamellar sheet-like devices of the present invention may optionally contain a silicone containing emulsifier or surfactant. A wide variety of silicone emulsifiers are useful herein. These silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains containing moieties derived from both ethylene oxide and propylene oxide. Other examples include alkyl-modified dimethicone copolyols, i.e., compounds which contain $C_2$-$C_{30}$ pendant side chains. Still other useful dimethicone copolyols include materials having various cationic, anionic, amphoteric, and zwitterionic pendant moieties.

Other Optional Ingredients

The devices of the present invention can comprise a wide range of other optional components. These additional components should be pharmaceutically acceptable. The

CTFA Cosmetic Ingredient Handbook: Second Edition, 1992, incorporated by reference herein in its entirety, describes a wide variety of cosmetic and pharmaceutical ingredients commonly used in the cosmetic industry, which are suitable for use in the compositions of the present invention. Non-limiting examples of functional classes of ingredients are described at page 537 of this reference. Examples of these and other functional classes include: abrasives, absorbents, antibiotics, anticaking agents, anti-dandruff agents, anti-perspirant agents, antioxidants, biological additives, bleach activators, brighteners, builders, buffering agents, chelating agents, chemical additives, colorants, cosmetics, cleansers, denaturants, dental treatments, deodorants, desquamation actives, depilatories, drug astringents, dyes, dye transfer agents, enzymes, external analgesics, flavors, film formers, fragrance components, insect repellants, mildewcides, opacifying agents, oxidative dyes, oxidising agents, pest control ingredients, pH adjusters, pH buffers, pharmaceutical actives, plasticizers, preservatives, radical scavengers, skin, hair or nail bleaching agents, skin, hair or nail conditioners, skin, hair or nail penetration enhancers, stabilisers, surface conditioners, reducing agents, temperature depressors, and warmth generators.

Also useful herein are aesthetic components such as colorings, essential oils, and skin, hair or nail healing agents. Other optional materials herein include pigments. Pigments suitable for use in the compositions of the present invention can be organic and/or inorganic. Also included within the term pigment are materials having a low colour or lustre such as matte finishing agents, and also light scattering agents. Examples of suitable pigments are iron oxides, acyglutamate iron oxides, titanium dioxide, ultramarine blue, D&C dyes, carmine, and mixtures thereof. Depending upon the type of composition, a mixture of pigments will normally be used.

The pH of the pre-formed, unilamellar sheet-like devices herein is preferably from about 3 to about 9, more preferably from about 4 to about 8.

The pre-formed, unilamellar sheet-like devices of the present invention are patches or masks having a size and shape adapted to conform to a desired target area. Thus, devices according to the present invention may have sizes ranging from a surface area of about

0.25cm$^2$ to about 1,000cm$^2$. Preferably, at least one surface dimension of the device, preferably two surface dimensions of the device, is/are greater than the depth of the device, with preferred ratios of surface dimension(s) to depth of the device of about 2:1 to about 100:1, more preferably about 5:1 to about 50:1.

The term "surface dimension" as used herein, means a dimension in the x- or y-axes, depth being measured along the z-axis. The exact size and shape will depend upon the intended use and product characteristics. The pre-formed sheet-like devices herein are suitable for topical application to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, hands, arms, feet, or human torso. The devices herein may be, for example, square, circular, rectangular, oval, or other shapes which are composites of these, such as shapes that could be described as "semi-circle", "donut", or others. Devices shaped to fit the face have a surface area ranging from about 0.25 cm$^2$ to about 500 cm$^2$, preferably from about 1 cm$^2$ to about 400 cm$^2$. The patch or mask devices according to a third aspect of the invention have a thickness of from about 0.5mm to about 20mm, preferably from about 1mm to about 5mm. The patch or mask devices according to a second aspect of the invention have a thickness of from about 0.5mm to about 20mm, preferably from about 0.5mm to about 3mm in their delineated thickened region(s) and have a thickness of from about 0.5mm to about 17.5mm, preferably from about 0.5mm to about 2.5mm in their delineated thinner region(s).

The pre-formed, sheet devices of the present invention may also be made and used in the form of handwear, footwear, or a body wrap. Typically, the handwear will comprise a glove for the hand or any portion thereof, and the footwear will comprise a sock for the foot or any portion thereof. As used herein, the term "glove" is meant to be inclusive of "mitten." Preferably, the handwear comprises a glove body comprising a middle section, from one to four finger receptacles connected with the middle section, a thumb receptacle connected with the middle section, a palm side and an opposite back side. Preferably, the footwear comprises a sock body forming a tubular foot portion having a closed end and an open end. The inventive devices may also be made or used in the form of a body wrap. The body wrap is wrapped radially around any body part having a longitudinal axis. Its

ends may communicate with each other, or its length may be shortened so as to only wrap partially around. In either case, the wraps should exhibit excellent conformity to the shape of the body part. Typically, such body parts will include the user's back, upper arm, lower arm, upper leg, lower leg, neck, and torso.

Following application of the device, it may be left on the target area for about 3 hours, preferably about 1 hour, more preferably less than 15 minutes. The pre-formed, unilamellar sheet-like device can then be removed all in one piece.

Depending on the benefit agent (or benefit agents) contained therein, the devices of the present invention may have at least one of the following uses; hydrating the skin, hair or nails, smoothing fine lines and wrinkles; cosmetically treating acne; firming the skin, strengthening; softening; exfoliating; improving and/or evening skin tone and/or texture; skin, hair or nail lightening; tanning; reducing the appearance of pores; absorbing or controlling secretions; protecting and/or soothing the skin, hair or nails, muscles, aches or pains; reducing puffiness, and/or dark circles; stimulating wound healing; warming, refreshing or cooling the skin, hair or nails; relieving inflammation; brightening the complexion; decongesting; reducing swelling; treating dermatological conditions; cushioning; purifying; fragrancing; reducing bacterial or micro-organism growth; healing; repelling insects; removing unwanted hair, dirt, or make-up; and colouring or bleaching the target area to which the device is applied. Preferably, the pre-formed unilamellar sheet-like devices herein are cosmetically used for hydrating the skin, hair or nails; smoothing fine lines and wrinkles; and improving and/or evening the skin tone and/or texture.

Methods of Production

By subjecting the at least one benefit agent and the at least one gellable polymeric gel forming agent to a gelling step, a pre-formed, unilamellar sheet-like device which is self-supporting, is formed. The nature of the gelling step is dependent on the nature of the polymeric gel forming agent used. For example, the gelling step may involve the addition of metal ions to cross-link a polymer solution or it may involve irradiation with ultraviolet rays to produce a self-supporting gel.

In many cases, the gelling step is achieved via cooling. This involves heating a liquid, the at least one benefit agent and the at least one gellable polymeric gel forming agent, together with any other optional ingredients present (or gel-forming mixture), to a first temperature above the gel point of the gel-forming mixture, to solubilize the gel-forming mixture; placing the gel-forming mixture in a suitably shaped mould; and gelling the gel-forming mixture at a second temperature, which is cooler than the first temperature at or below the gel point of the gel-forming mixture to produce a unilamellar self-supporting device. In an alternative embodiment, the at least one benefit agent and the at least one gellable polymeric gel forming agent and any optional components present are heated, once placed in the suitably shaped mould.

In forming the self-supporting device, the components may be added together or sequentially in any order. The order of adding the components may depend on the properties and characteristics thereof. Preferably, the at least one benefit agent and the at least gellable polymeric gel forming agent are sufficiently dissolved in the liquid before any other components are added. By the term "sufficiently dissolved" is meant that the gel-forming mixture appears substantially or completely transparent. The temperature of the gel-forming mixture is maintained above the gel point until all of the components are added. In alternative embodiments, it may be beneficial to begin to lower the temperature of the gel-forming mixture prior to adding the final components.

The at least one benefit agent and the at least one gellable polymeric gel forming agent are maintained at an elevated temperature for an effective length of time. An "effective" length of time is sufficient to allow the at least one gellable polymeric gel forming agent sufficient time to dissolve completely (or substantially) in the liquid.

In a preferred embodiment, the self-supporting device may be produced through injection moulding. It is believed that the device so produced is stronger due to the smoother finish of the surface, which provides a greater resistance to tearing. An injection moulding process for producing a self-supporting device comprises the steps of injecting the gel-forming mixture into a suitably shaped mould, the mixture being maintained prior to the injection step at a first temperature above the gel point of the gel-forming mixture; and

cooling the gel-forming mixture in the suitably shaped mould to a second temperature below the gel point of the gel-forming mixture, to form a unilamellar self-supporting device.

In an alternative injection moulding process, the at least one benefit agent and the at least one gellable polymeric gel forming agent and any other optional components, if present, are added sequentially in any order or all at once. For injection moulding, the at least one benefit agent and the at least one gellable polymeric gel forming agent is adapted to be fluid enough to enable it to be readily supplied to a die by any conventional means, in addition to injection moulding processes. Lubricants may be added to assist in feeding the gel-forming mixture along the bore of an extruding barrel.

The gel-forming mixtures may be supplied to the suitably shaped mould by any other variety of well known technique including gravity feed systems and pneumatic or mechanical injection systems. Injection moulding is the most preferred technique because of the fluidity and low processing temperatures of the mixtures. A very wide range of moulding pressures may be employed. Generally, the moulding pressure is between about $10^5$ Pa (1 atmosphere) and about $5x10^6$ Pa (50 atmospheres), although higher or lower pressures may be employed depending on the moulding technique used. An advantage of the present invention is the ability to mould the devices of the present invention using low pressures.

When gelling is achieved via cooling, the moulding temperature must, of course, be at or below the gel point of the gel-forming mixture in order to produce a self-supporting device. The appropriate mould temperature can be achieved before, during, or after the mixture is supplied to the mould. After the device is moulded and cooled to a temperature below the gel point, the device is removed from the mould. The device, being self-supporting, requires no special handling during removal from the mould.

In a device according to a first or second or fourth aspect of the invention wherein the device has a non-planar topography on at least one of the first and second surfaces, preferably the second surface, of the device, the non-planar topography comprising at least two delineated regions not simultaneously having the same mean thickness, the

mould has at least one of first and second mould surfaces, the at least one of first and second mould surfaces being the negative image of the at least one of first and second surfaces of the device itself and the at least one of the first and second mould surfaces being a negative image of the non-planar topography. The non-planar topography is of a freely selectable shape including, but not limited to those illustrated in Figures 1-4, 6-7, 8-9 and 10-12 of the accompanying drawings. If the non-planar topography has periodicity, the at least one of the first and second mould surfaces has periodicity, which confers a negative image of the periodicity to the at least one of first and second surfaces of the device itself.

According to a first and third aspect of the present invention, the device has at least one of the first and second surfaces, preferably the second surface, having a non-planar topography comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm. If the non-planar topography has periodicity, the texturing surface has periodicity, which confers a negative image of the periodicity to the at least one of first and second surfaces of the device itself. The method for its production involves preparing a gel-forming mixture comprising at least one benefit agent and at least one polymeric gel forming agent and the optional components, if present, and heating said mixture to a first temperature above the gel point of the mixture, to solubilise the gel-forming mixture; placing the mixture in a suitably shaped mould having at least one of first and second mould surfaces being the negative image of at least one of the first and second surfaces of the device itself; on at least one of which first and second mould surfaces is pre-positioned a texturing surface whose negative image has a texture defined by $R_a$ of greater than 10μm; gelling the mixture at a second temperature cooler than the first temperature at or below the gel point of the gel-forming mixture; and removing the, or each, texturing surface from the device. The removing step may take place during or after the gelling step. The texturing surface is selected from the substrates described hereinabove, provided that the negative image of an outer surface of the substrate has $R_a$ of greater than 10μm. Formed films are the preferred texturing surfaces.

In an alternative embodiment, the mixture is heated once placed in the mould. In a further alternative embodiment, the at least one of the first and second mould surfaces is textured to form the texturing surface by an etching process or any other process known in the art.

When the non-planar topography has periodicity on both the first and second surfaces of a device, either as a result of the mould surface or the texturing surface having periodicity, the pattern produced by the periodicity on both surfaces may be aligned or staggered. Preferably, the pattern is staggered.

The present method also includes a method of producing a pre-formed, unilamellar sheet-like device according to the first, second and third or fourth aspects of the invention, the method comprising preparing a gel-forming mixture comprising at least one benefit agent and at least one polymeric gel forming agent and the optional components, if present; heating the mixture to a first temperature above the gel point of the mixture, to solubilize the gel-forming mixture; placing the mixture in a suitably shaped mould having at least one of first and second mould surfaces being the negative image of at least one of the first and second surfaces of the device itself, the topography of the at least one of the first and second device surfaces defining at least two delineated regions simultaneously not having the same mean thickness; on at least one of which first and second mould surfaces is pre-positioned a texturing surface whose negative image has a texture defined by $R_a$ of greater than 10μm; gelling the mixture at a second temperature cooler than the first temperature at or below the gel point of the gel-forming mixture; and removing the, or each, texturing surface from the device.

In an alternative embodiment, the mixture is heated once placed in the mould. In a further alternative embodiment, the at least one of the first and second mould surfaces is textured to form the texturing surface by an etching process or any other process known in the art.

Methods Of Evaluation

Gel Compressive Rupture Test

The mechanical properties of the pre-formed unilamellar sheet-like devices of the present invention are measured via compressive failure testing of the gel. Parameters of interest are the gel strength (measured via the compressive force required to rupture a moulded gel

cylinder) and the gel flexibility (measured as the extent of gel compression at the point of rupture). A more detailed description of the test method follows.

Compressive failure testing is performed using a Stable Micro Systems (SMS) Texture Analyser (TA), model TA-XT2i available from Stable Micro Systems Ltd (Godalming, Surrey, UK). The system is controlled through SMS's Texture Expert Exceed software (version 2.03) running within Windows-98. A 100 mm diameter aluminum compression plate (P-100 probe) is attached to a 50 Kg load cell. This is mounted within the TA Probe Carrier, the extended arm whose vertical travel is under computer control.

To create test samples, a gel formulation of interest is prepared as described below. Gel discs of a precise cylindrical-solid shape (26 mm diameter by 12 mm depth) are formed in correspondingly shaped moulds. The moulds with sample are hermetically sealed against evaporation during storage. These gel discs are stored at ambient temperature overnight. Each gel disc is removed from its mould just prior to testing and visually inspected for defects. Any gel discs with defects (e.g. trapped air bubbles) are discarded as these defects may impact the measured mechanical properties. The non-defective gel disc is then centered under the P-100 compression plate.

The Texture Expert Exceed software is set-up in Force / Compressive mode. The compression plate is pre-set to a starting height of 12.0 mm. Its rate of descent is set to 0.8 mm/second and total travel distance set to 10.8 mm (i.e. measurement stops when the gel disc is compressed by 90% of its original height). Data is automatically collected on force and position of the compression plate at the rate of 200 pps (points per second). The software is pre-set to mark compression plate position at the maximum force achieved. This maximum force is the rupture strength, that is, the force required to rupture the gel disc. The distance travelled by the plate from its original starting height to the point of gel rupture represents the extent of deformation of the gel. The maximum force at the point of rupture is averaged across samples (typically 5 replicates) and reported in Newtons.

The uni-axial deformation (compression) at the gel's point of rupture is expressed as a percent of its original moulded height, i.e.

$$\% \text{ Compression} = \frac{\text{distance travelled by plate (in mm) at maximum force}}{} \times 100$$

12 (original sample height in mm)

If gel rupture has not occurred by the end of the 10.8 mm stroke, (i.e. 90% compression), the gel is classified as 'non-rupturing' under these test conditions.

Surface Roughness

Surface topography was measured using a CADEYES Surface Analysis System (Medar, USA), a moire interferometry technique, configured with a 30.7 μm x-axis resolution, 35.8 μm y-axis resolution, and 1.6 μm z-axis resolution. Textured surfaces representative of devices of the first or third aspects of the invention were prepared by making negative silicone casts (Silflo Silicone Impression Material; Flexico Developments,UK) of texturing surfaces useful in the production of pre-formed, unilamellar sheet-like devices according to a first or third aspect of the present invention. Silicone casts were used instead of actual pre-formed, unilamellar sheet-like devices because the optical properties of the silicone casting material are more suitable for optical surface analysis.

Silicone casts were prepared as follows:

1. A 2.54 cm (1 inch) diameter circle of silicone paste was mixed thoroughly with 1 drop of catalyst for approximately 1 minute.
2. Using a spatula, the silicone mixture was applied to the texturing surface and allowed to cure at room/ambient temperature for approximately 7 minutes.
3. After curing, the silicone cast was removed from the texturing surface and analysed.

The data reported for describing the surface roughness of the silicone cast representative of the textured surface of devices of a first or third aspect of the invention include $R_a$, surface-based average deviation from a best fit plane, wherein $R_a = 1/n \sum_{i=1}^{n} z_i$ where z, at a point, is the absolute value of the calculated best fit elevation at a point minus the measured elevation at that point; the calculated best fit elevation at the point is the elevation of the best fit plane to the measured surface at that point. The data reported for describing the surface roughness also include $R_q$, surface-based root mean square deviation from a best fit plane and $R_z$, 10-point roughness.

$R_q$ is surface-based root mean square deviation from a best fit plane $R_q = \sqrt{1/n\sum_{i=1}^{n} z_i^2}$

$R_Z$ is ten-point roughness averaged over all scan lines in the x-direction,

$$R_Z = ((S_1 + S_3 + S_5 + S_7 + S_9) - (S_2 + S_4 + S_6 + S_8 + S_{10}))/5$$

where $S_1$,, $S_3$, $S_5$, $S_7$, $S_9$ are the 5 highest peaks from the best fit plane along the scan line and $S_2$, $S_4$, $S_6$, $S_8$, $S_{10}$ are the 5 lowest valleys from the best fit plane along the scan line. The best fit plane as described herein is automatically calculated by the CADEYES Surface Analysis System, i is an index referring to a particular point analysed and n is the total number of points analysed, e.g., for a $1cm^2$ area, n is 90,987.

Although the surface topographies of these samples were acquired using a moire interferometry technique, any appropriately configured (x and y axis resolution less than 40 μm; z axis resolution less than 2 μm), surface profiling technique (*e.g.*, stylus profilometry, laser profilometry, or fringe projection) could be used to acquire the surface topographies to produce these data. An alternative method of measuring $R_a$ and $R_q$ is via the line based method described in ISO4287 (1997) where $R_a$ is defined as the arithmetical mean deviation of the assessed profile and $R_q$ is defined as the root mean-square deviation of the assessed profile.

Surface Glossiness

A texturing surface was placed on a gel-forming mixture comprising 0.83% agarose, 0.3% Kelgum® (1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA), 20% glycerin, 10% niacinamide, 1% panthenol, 5% butylene glycol, 0.15% Nipagin A (ethyl paraben, supplied by Nipa Laboratories, Inc., Wilmington, DE, USA), 0.1% Hampene $Na^2$ (disodium EDTA, supplied by Hampshire Chemical, Lexington, MA, USA), 62.62% deionized water. The texturing surface was removed once the gel structure has set. Gloss measurements (i.e. surface reflectance) were then measured on the textured surface of such a pre-formed, unilamellar sheet-like device according to the first or third aspect of the invention, on the opaque (black) section of a Leneta Card, available from The Leneta Company. Measurements of % surface

reflectance were taken using a BYK-Gardner Micro Tri-Gloss meter (BYK Gardner, Sliver Spring, MD) set to read at 20 degrees (20°), 60 degrees (60°) and 85 degrees (85°).

Gel Transparency

Gel transparency was measured by assessing the visibility of printed text through a device according to the present invention. The printed text was prepared by printing the English alphabet (capital letters) onto transparency film (Universal Office Supplies) using Microsoft Word Arial font and a LaserJet 4 Plus printer (Hewlett Packard) fitted with a black ink cartridge. Printed transparency films were prepared in font sizes ranging from 4 points to 28 points. The printed transparency films were then laid over white paper sheets to ensure a uniform background and all samples were assessed under normal indoor lighting conditions.

A sample of the gel of interest was moulded to produce a gel disc with a thickness (depth) of 7 mm. This gel disc was placed onto the transparency film printed with 4 font size and the visibility of the printed alphabet was assessed through the disc of gel. If the text was not legible through the gel disc, the disc was transferred to the next largest font sizeand the assessment repeated. This process was repeated until a font size was reached that was legible through the gel. The smallest font size legible through the gel sample was then assigned the "transparency threshold" for that gel. The preferred "transparency threshold" for the gels used to make the devices of the present invention is 10 font size, more preferred is 7 font size and especially preferred is 4 font size.

Examples

The invention is illustrated by the following examples.

Examples 1 - 3

| | 1 | 2 | 3 |
|---|---|---|---|
| Ingredient | % w/w | % w/w | % w/w |
| Agarose | - | 0.4 | 0.8 |
| Locust Bean Gum | - | 0.27 | - |
| Konjac Mannan | 0.3 | - | - |
| Xanthan Gum | 0.1 | 0.13 | - |

| | | | |
|---|---|---|---|
| Kelgum™[1] | - | - | 0.3 |
| Gellan Gum | 1.0 | 0.4 | - |
| Glycerin | 20.0 | 20.0 | 15.0 |
| Butylene Glycol | 5.0 | - | 8.0 |
| Panthenol | 1.0 | 2.0 | 2.0 |
| Niacinamide | - | 5.0 | - |
| Sucrose Polycottonseedate | - | - | 0.5 |
| Polysorbate 60 | - | - | 0.2 |
| Dimethicone Copolyol | 0.02 | 0.02 | - |
| Benzyl Alcohol | - | 0.3 | 0.2 |
| Ethyl Paraben | 0.2 | 0.1 | - |
| Propyl Paraben | - | 0.05 | - |
| Disodium EDTA | - | 0.1 | - |
| Calcium Chloride | 0.1 | 0.08 | - |
| Water | to 100 | to 100 | to 100 |
| **Force To Rupture/N** | **82** | **73** | **102** |
| **% Compression** | **26** | **44** | **58** |
| *Substrate* | *Paper*[2] | - | - |

[1]Kelgum™ is a 1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA.

[2]Paper is "Kimwipes EX-L" from Kimberley-Clark Corp., Roswell, GA, USA.

The polysaccharide gums are mixed with water to form a uniformly dispersed mixture (this can be facilitated by pre-dispersing the polysaccharides in a non-solvent e.g. polyhydric alcohol) and any additional components are added. The mixture is heated with stirring to a first temperature above the gel point of the mixture (ca. 90°C) to fully hydrate the polysaccharide gums. The liquid gel is then dispensed into a suitably shaped mould (Example 3). The devices of Examples 1 and 2 are injection moulded into a suitably shaped mould. Injection moulding is preferred. This eliminates any defects which may

be introduced by cutting the gel and so improves the robustness of the device. Injection moulding also allows the device to be readily formed into a three-dimensional structure. The liquid gel is then cooled to a second temperature cooler than the first temperature at or below the gel point of the mixture (ambient temperature) to set up the gel structure. The device may then be removed from the mould. The devices of Examples 1-3 are illustrated in, respectively, Figures 1-3 of the accompanying drawings. The devices herein are then packaged into materials which have low water vapour permeability to minimise drying out of the device during storage. Suitable packaging for devices herein include sachets or sealed trays. If the device is packaged in a sachet, it is preferably protected prior to use. This protection can be provided by a substrate or by a release liner such as a plastic film, which provides easy release for the device.

If a substrate is to be used (Example 1), this may be placed in the suitably shaped mould prior to dispensing the gel or it may be placed on the surface of the liquid gel during the cooling stage.

In some compositions, metal ions (e.g. $Ca^{2+}$, $K^{+}$) may be included in the formulation to increase the gel strength of the device (Examples 1 and 2). In this case, the metal ions are added in the form of an aqueous solution and are stirred into the liquid gel immediately before the dispensing step.

The above method may be modified as necessary depending on the nature of any additional components. For example, if non-aqueous components are present, the liquid gel may be homogenised immediately prior to moulding or casting to ensure dispersion of the non-aqueous components. Similarly, if heat sensitive ingredients are incorporated, the formulation should be cooled to an appropriate temperature (dependent on the ingredient) after the gum hydration step and the heat sensitive ingredient added at this stage.

The liquid gel may be de-gassed, e.g. by vacuum, to remove air bubbles dispersed within the liquid. This de-gassing step, if followed, would be the final step immediately prior to dispensing the liquid gel.

As shown above, the pre-formed, sheet-like devices herein have excellent strength and flexibility.

**Example 4**

A formulation of a pre-formed, sheet-like device has been prepared containing 50/50 (weight/weight) silicone gel forming agent and ascorbic acid and derivatives thereof as a benefit agent. The formulation is prepared by condensing at 115 to 120°C, in the presence of 0.025 parts anhydrous ammonia, 67 parts of a 70wt% xylene solution of a siloxane resin copolymer consisting essentially of $(CH_3)_3SiO_{1/2}$ units and $SiO_{4/2}$ units in a molar ratio of approximately 0.75:1 and containing approximately 2.7 weight percent hydroxyl based on solids as determined by FTIR (ASTM E-168), 31 parts of a hydroxyl terminated polydimethylsiloxane having a viscosity of about 13,500 cP (mP.s) at 25°C and 2 parts of xylene. Following the condensation reaction, the mixture was heated to 140°C for 1 hour to remove any excess ammonia.

The silicone mass was then mixed with an equal weight of ascorbic acid and derivatives thereof (ultrafine powder, Hoffman-LaRoche) for 17 minutes using a Lee stainless steel tilt kettle with a built-in Eppinbach high shear mixer.

The silicone solution is transferred to a suitably shaped mould and allowed to air dry overnight to allow evaporation of the solvents. The resulting device is removed from the mould and packaged. This silicone-containing pre-formed, sheet-like device was found to be suitable for delivering ascorbic acid and derivatives thereof as a benefit agent to the skin, hair or nails.

**Example 5**

50 parts (dry weight) of medical grade acrylic pressure sensitive adhesive (Draize scale score 0-1), dissolved in ethyl acetate and toluene, is mixed with 50 parts (ascorbic acid and derivatives thereof and sodium ascorbate, both as dry powders, in a 1:22 (wt/wt) ratio) to form the cosmetically effective adhesive matrix. It is transferred to a suitably shaped mould and then cured at 121.2°C. This pre-formed, sheet-like device was found to be suitable for delivering at least one benefit agent to the skin, hair or nails.

**Example 6**

| **Ingredient** | % w/w |
|---|---|
| Agar | 0.6 |
| Agarose | 0.3 |
| Locust Bean Gum | 0.1 |
| Konjac Mannan | 0.2 |
| Xanthan Gum | 0.1 |
| Glycerin | 15.0 |
| Panthenol | 3.0 |
| Polysorbate 60 | 0.08 |
| Benzyl Alcohol | 0.3 |
| Ethyl Paraben | 0.1 |
| Propyl Paraben | 0.05 |
| Water | to 100 |
| **Force To Rupture/N** | **78** |
| **% Compression** | **58** |

The polysaccharide gums are mixed with water to form a uniform dispersion and any additional components are added. Formation of a uniform dispersion can be facilitated by pre-dispersing the polysaccharides in a non-solvent, for example, polyhydric alcohol. The mixture is heated with stirring to about 90°C to fully hydrate the polysaccharide gums. The liquid gel may be de-gassed, for example, by vacuum, to remove air bubbles dispersed within the liquid. The liquid gel is then dispensed into a suitably shaped mould and is then cooled to ambient temperature to set up the gel structure. The device may then be removed from the mould. Alternatively, the liquid gel may be cast into a sheet and an appropriately shaped device may be cut from the gel sheet. The device of Example 6 is illustrated in Figure 4 of the accompanying drawings. The device is then packaged into materials which have a low water vapour permeability to minimise drying out of the device during storage.

Replicates of the device were then assessed for surface roughness (Table 1) and surface reflectance (Table 2) using a variety of texturing surfaces. The texturing surface may be brought into contact with the device, either before or during gelling of the liquid gel.

**Table 1 - Surface Roughness of Silicone Casts**

| Texturing Surface | $R_a$ | $R_q$ | $R_z$ |
|---|---|---|---|
| None | 4.85 | 6.32 | 14.13 |
| 60 mesh, X-7189[2] | 21.10 | 34.37 | 93.93 |
| 40 hex, X-2S137[2] | 92.27 | 133.51 | 353.78 |
| VFE, 3.4mil, X-15928[2] | 160.22 | 189.26 | 441.45 |
| DRI-WEAVE, pattern #35/7 | 171.18 | 206.07 | 527.44 |
| Hydroformed film[1] | 315.26 | 360.85 | 786.01 |

[1] A hydroformed film having both micro and macro apertures as described in US-A-4,609,518 to Curro et al, issued September 2, 1986. Preferably, the macro apertures have a teardrop pattern with 12% open area disposed in a pattern having 24 macro apertures/$cm^2$ wherein the base of each macro aperture is 1.54$mm^2$, the tip is 0.3$mm^2$ in diameter and the micro apertures are formed on a screen having a 100 mesh pattern.

[2] from Tredegar Film Products, 1100 Boulders Parkway, Richmond, VA, USA 23225.

All of the texturing surfaces are, as is preferred, formed films, described above in connection with substrates.

The negative image of all suitable texturing surfaces as defined here will have $R_a$ of greater than 10μm, preferably greater than 20μm, when measured as described above. The preferred range for a negative image of a texturing surface for the devices of the present invention is $R_a$ greater than 10μm and less than 316μm when measured as described above. The negative image of a suitable texturing surface as defined here will have Rq of greater than 7μm, preferably greater than 30μm and/or most preferably less than 375μm. The negative image of a suitable texturing surface will have $R_Z$ of greater

than 15μm, preferably greater than 75μm, more preferably greater than 90μm and/or most preferably less than 800μm.

**Table 2 - % Surface Reflectance of Textured Surface**

| Texturing Surface | 20° | 60° | 85° |
|---|---|---|---|
| None | 48 | 64.8 | 72.8 |
| 60 mesh, X-7189[2] | 0.9 | 4.0 | 4.3 |
| 40 hex, X-2S137[2] | 1.8 | 7.2 | 4.3 |
| DRI-WEAVE, pattern # 35/7 | 2.5 | 14.3 | 17.2 |
| Hyrdroformed film[1] | 0.3 | 0.8 | 0.35 |
| VFE, 3.4mil, X-15928[2] | 2.7 | 23.6 | 19.2 |

[1] A hydroformed film having both micro and macro apertures as described in US-A-4,609,518 to Curro et al, issued September 2, 1986. Preferably, the macro apertures have a teardrop pattern with 12% open area disposed in a pattern having 24 macro apertures/$cm^2$ wherein the base of each macro aperture is 1.54$mm^2$, the tip is 0.3$mm^2$ in diameter and the micro apertures are formed on a screen having a 100 mesh pattern.

[2] from Tredegar Film Products, 1100 Boulders Parkway, Richmond, VA, USA 23225.

All textured surfaces as defined herein will have preferred levels of gloss in the range of < 40, < 58, and < 65 for the 20°, 60° and 85° geometries, respectively. The preferred ranges of gloss for devices of the present invention are 0-10, 0-30 and 0-25 for the 20°, 60° and 85° geometries, respectively. The most preferred gloss ranges are 0-5, 0-25 and 0-20 for the 20°, 60° and 85° geometries, respectively.

**Example 7**

| | %(w/w) |
|---|---|
| Agarose | 0.9 |
| Glycerine | 20.0 |
| Butylene Glycol | 5.0 |

| | |
|---|---|
| Ethyl Paraben | 0.15 |
| Disodium EDTA | 0.1 |
| Water | to 100 |

The polysaccharide gums are mixed with water to form a uniform dispersion and any additional components are added. The formation of a uniform dispersion can be facilitated by pre-dispersing the polysaccharides in a non-solvent, for example, polyhydric alcohol. The gel-forming mixture is heated with stirring to about 90°C to fully hydrate the polysaccharide gums. Following de-gassing (by vacuum for example), the liquid gel-forming mixture is transferred to a suitably shaped mould (for example, a mould shaped to produce the patch device illustrated in Figures 6 and 7 of the accompanying drawings).

The gel transparency of the present device was assessed as described above - its transparency threshold is 4 font size.

Claims

1. A pre-formed, unilamellar sheet-like device (10, 110, 210, 310, 410, 510, 610, 710, 810) for delivering benefit agents to the skin, hair or nails, the device having a perimeter (12, 112, 212, 512, 612, 712, 812) defining first and second spaced-apart surfaces (14, 114, 214, 314, 414, 514, 614, 714, 814; 16, 116, 216, 316, 416, 516, 616, 716, 816); the device comprising at least one benefit agent and at least one polymeric gel forming agent; and the device having a non-planar topography on at least one of the first and second surfaces.

2. A pre-formed, unilamellar sheet-like device (10, 110, 210, 310, 510, 610, 710, 810) for delivering benefit agents to the skin, hair or nails, the device having a perimeter (12, 112, 212, 512, 612, 712, 812) defining first and second spaced-apart surfaces (14, 114, 214, 314, 514, 614, 714, 814; 16, 116, 216, 316, 516, 616, 716, 816); the device comprising at least one benefit agent and at least one polymeric gel forming agent; and the device having a non-planar topography on at least one of the first and second surfaces, the non-planar topography comprising at least two adjacent delineated regions (22, 122, 222, 322, 522, 622, 722, 822; 18, 118, 818; 20, 220, 320; 524, 624, 724) simultaneously not having the same mean thickness.

3. A device according to claim 2, wherein one of the at least two delineated regions comprises a rim (18, 118, 818) adjacent the perimeter (12, 112, 822).

4. A device according to claim 2 or 3, wherein one of the at least two delineated regions comprises at least one ridge (20, 220, 320) intermediate the perimeter (12, 212).

5. A device according to any one of claims 2 to 4, wherein one of the at least two delineated regions comprises an imprint of a symbol.

6. A device according to any one of claims 2 to 5, wherein the second surface is distal the skin, hair or nails, the second surface (16, 116, 216, 316, 516, 616, 716, 816) having the non-planar topography and comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm.

7. A device according to Claim 6, wherein the first surface is adjacent to the skin, hair or nails, the first surface (14, 114, 214, 314, 514, 614, 714, 814) having the non-planar topography comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm.

8. A method of producing a pre-formed, unilamellar sheet-like device according to any one of the preceding claims, the method comprising the steps of providing a gel-forming mixture, comprising at least one benefit agent and at least one gellable polymeric gel forming agent, in a mould having at least one surface that is the negative image of the, or each, non-planar topography, the non-planar topography comprising at least two delineated regions simultaneously not having the same mean thickness or a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm; or both; and thereafter gelling the gel-forming mixture.

9. A method according to claim 12, wherein the providing step is injection moulding.

10. A method according to claim 12 or 13, wherein the non-planar topography is on the second surface (16, 116, 216, 316, 516, 616, 716, 816) and comprises at least two delineated regions (22, 122, 222, 322, 522, 622, 722, 822; 18, 118, 818; 20, 220, 320; 524, 624, 724, 824) simultaneously not having the same mean thickness and a textured surface on at least one of the at least two delineated regions.

11. A method according to claims 12 to 14, wherein the device additionally comprises non-planar topography on the first surface (14, 114, 214, 314, 514, 614, 714, 814), the non-planar topography comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm.

12. A pre-formed, unilamellar sheet-like device (410, 810) for delivering benefit agents to the skin, hair or nails, the device comprising at least one benefit agent and at least one polymeric gel forming agent; and the device having a perimeter defining first and

second spaced-apart surfaces (414, 814; 414, 816), the first surface (414, 814) being adjacent, in use, the skin, hair or nails, and the second surface (416, 816) having a non-planar topography, the non-planar topography comprising a textured surface that is the negative image of a texturing surface, the negative image of the texturing surface having a texture defined by $R_a$ of greater than 10μm.

13. A device according to any one of claims 1 to 7 or 12, wherein the device is combined with a substrate.

14. A device according to any one of claims 1 to 7, 12 or 13, wherein the at least one polymeric gel forming agent is a water-soluble polymeric gel forming agent.

15. A device according to any one of claims 1 to 7 or 12 to 14, wherein the second surface (316, 416, 816) has a 20° gloss reading of less than 40, preferably less than 10, most preferably less than 5.

16. A device according to Claim 15 wherein the second surface has a 60° gloss reading of less than 58, preferably less than 30, most preferably less than 25.

17. A device according to Claim 15 or Claim 16, wherein the second surface has a 85° gloss reading of less than 65, preferably less than 25, most preferably less than 20.

18. A device according to any one of claims 12 to 17, wherein at least one of the first and second surfaces has at least two adjacent delineated regions simultaneously not having the same mean thickness.

19. A device according to any of claims 1 to 7 or 12 to 18, wherein the device has a transparency threshold of no greater than 10 font size, preferably no greater than 7 font size, most preferably no greater than 4 font size.

20. A device according to any of claims 1 to 7 or 12 to 18, in the form of a patch.

21. A device according to any of claims 1 to 7 or 12 to 20, which is packaged in a sealed, protective wrapper.

22. A method of producing a pre-formed, unilamellar sheet-like device according to any one of claims 1 and 12 to 21, the method comprising the steps of providing a gel-

forming mixture comprising at least one benefit agent and at least one gellable polymeric gel forming agent in a mould whose first mould surface has a topography which is the negative image of the first surface (814); of bringing a texturing surface into contact with the second surface (816) of the gel-forming mixture; gelling the gel-forming mixture; and removing the texturing surface from the device.

23. A method according to claim 22, wherein the topography of the first mould surface is a negative image of the first surface defining at least two delineated regions (822; 824) simultaneously not having the same mean thickness and/or a textured surface that is the negative image of a texturing surface having a texture defined by $R_a$ of greater than 10μm .

24. A method according to any of claims 8 to 11 or 22 or 23, which further includes the step of sealing the device in a protective wrapper.

25. A method of delivering at least one cosmetic benefit agent to the skin, hair or nails, the method comprising contacting the skin, hair or nails with a device according to any one of claims 1 to 7 and 12 to 21, the device comprising at least one cosmetic benefit agent and at least one polymeric gel forming agent.

26. A pre-formed, unilamellar sheet-like device according to any of Claims 1 to 7 or 12 to 21, in the form of a mask or patch having a size and shape adapted to conform to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, arms, hands, feet or human torso.

27. A pre-formed, unilamellar sheet-like device according to any of Claims 1 to 7 or 12 to 21, in a form selected from the group consisting of: handwear; footwear; and body wrap.

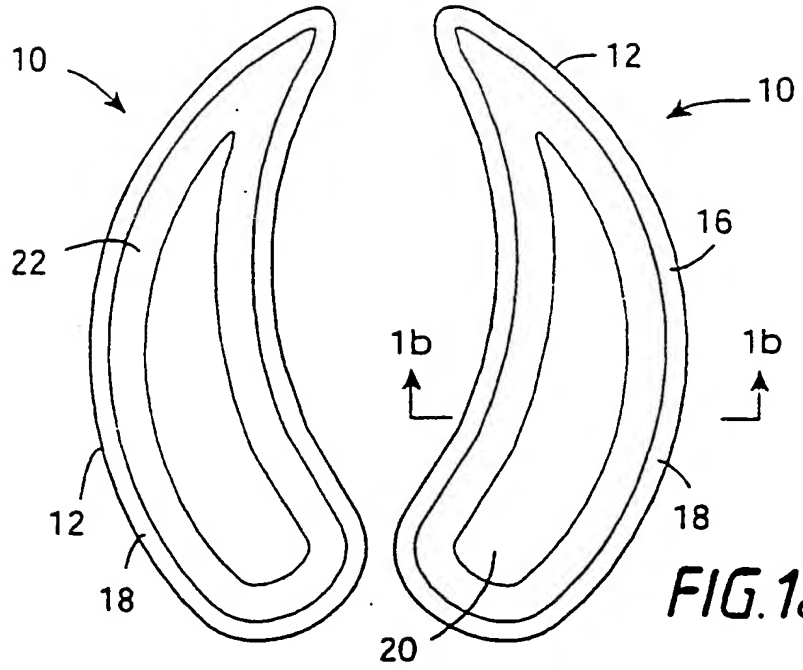



FIG. 1a

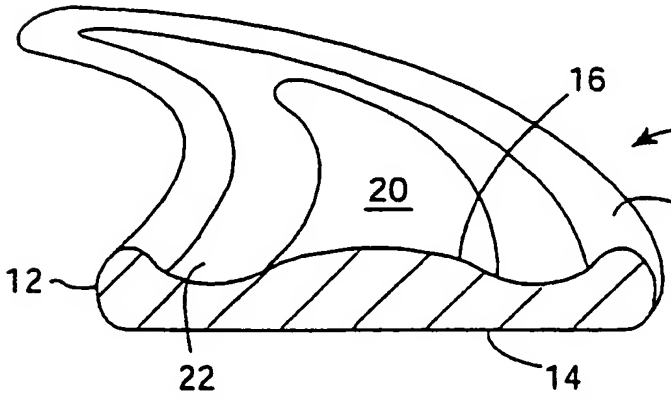



FIG. 1b

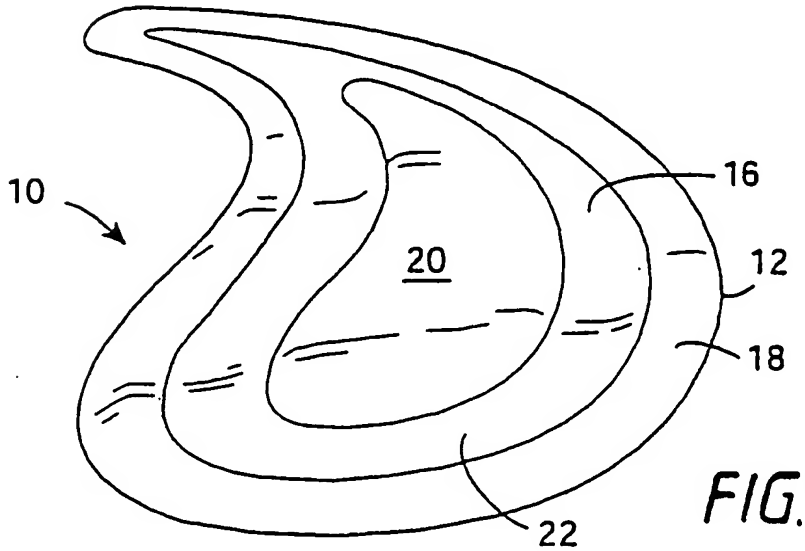



FIG. 1c

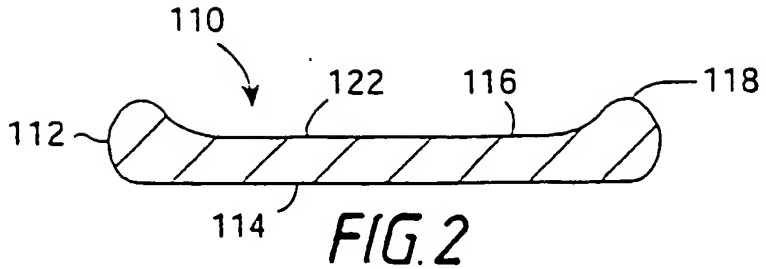



FIG. 2

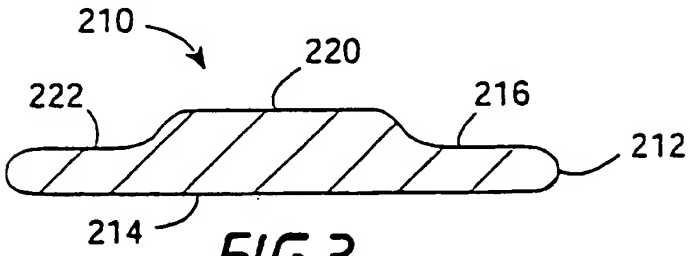



FIG. 3

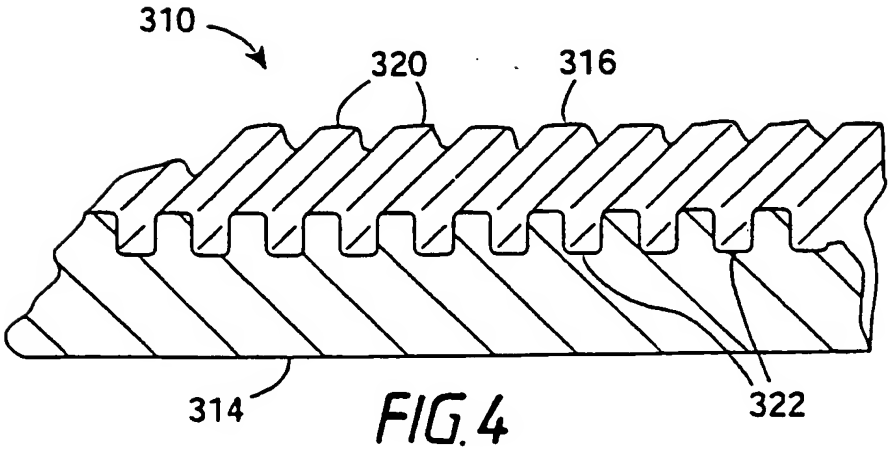



FIG. 4

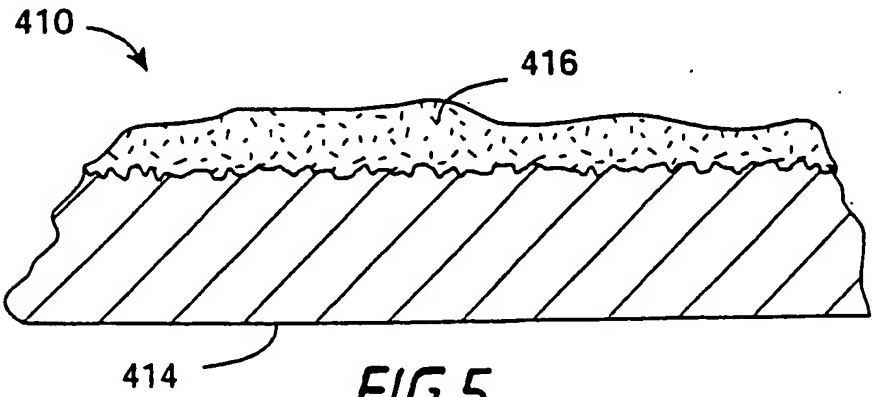



FIG. 5

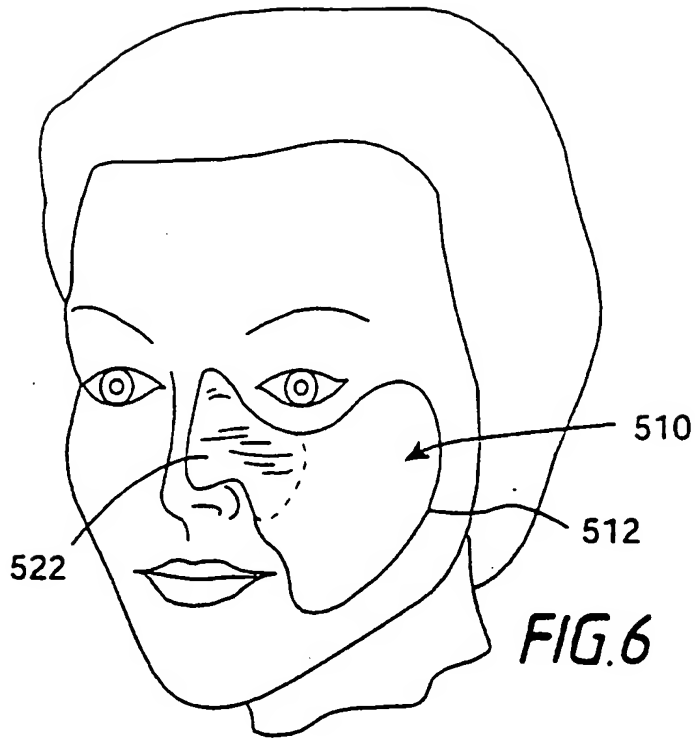



FIG.6

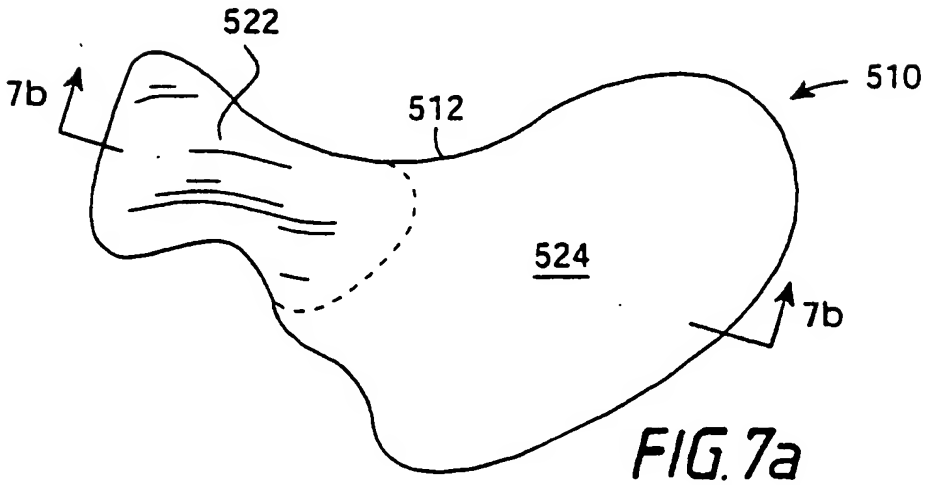



FIG.7a

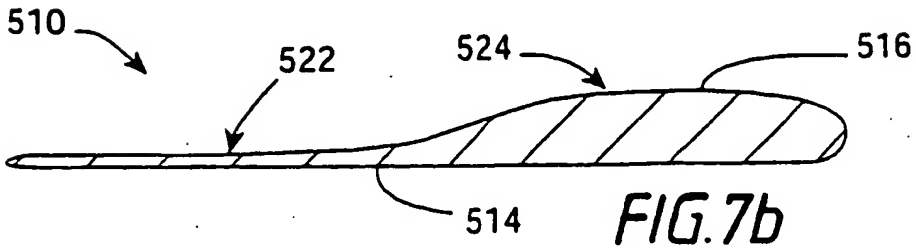



FIG.7b

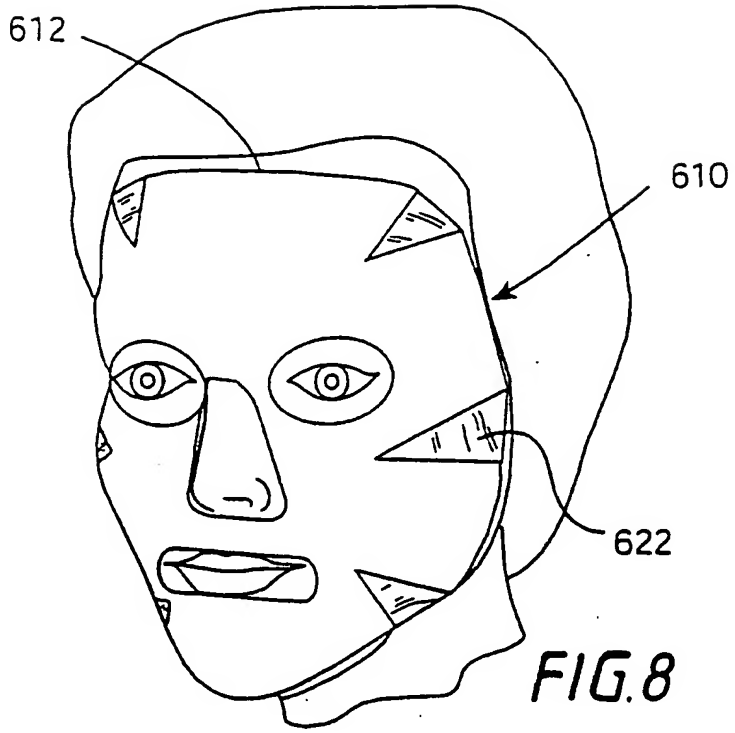



FIG.8

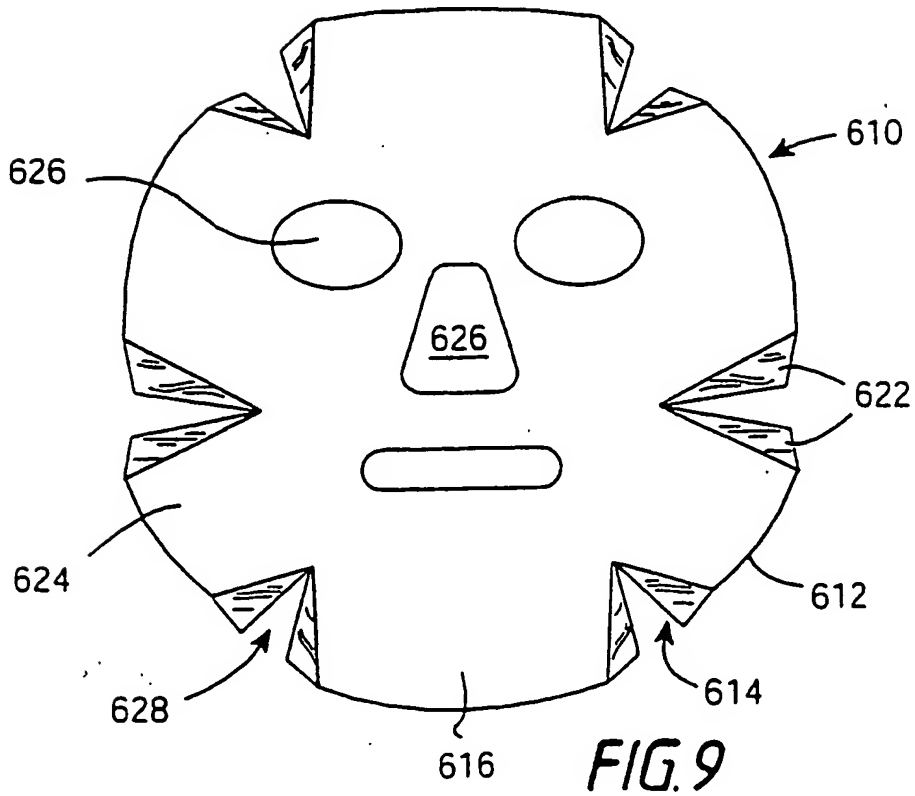



FIG.9

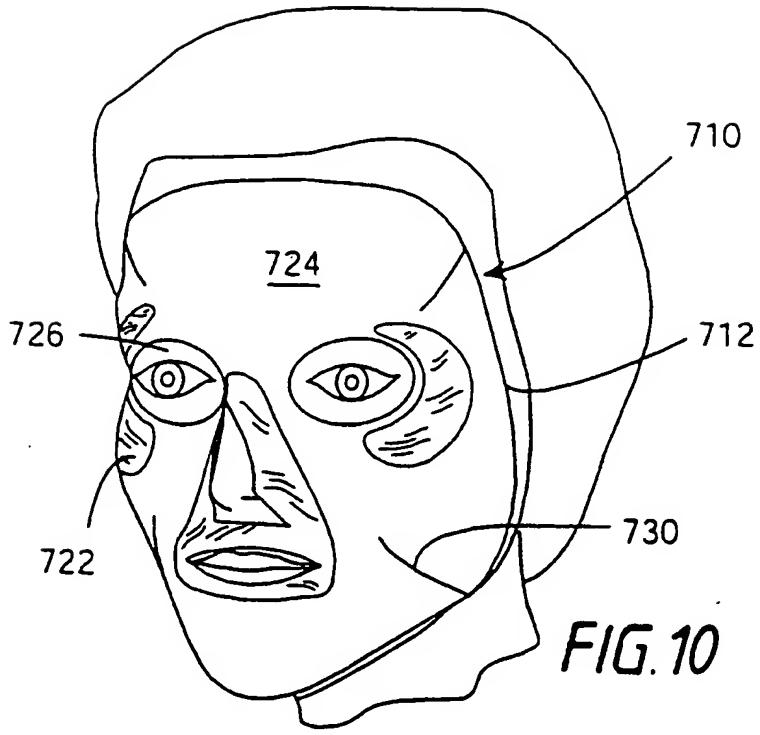



FIG. 10

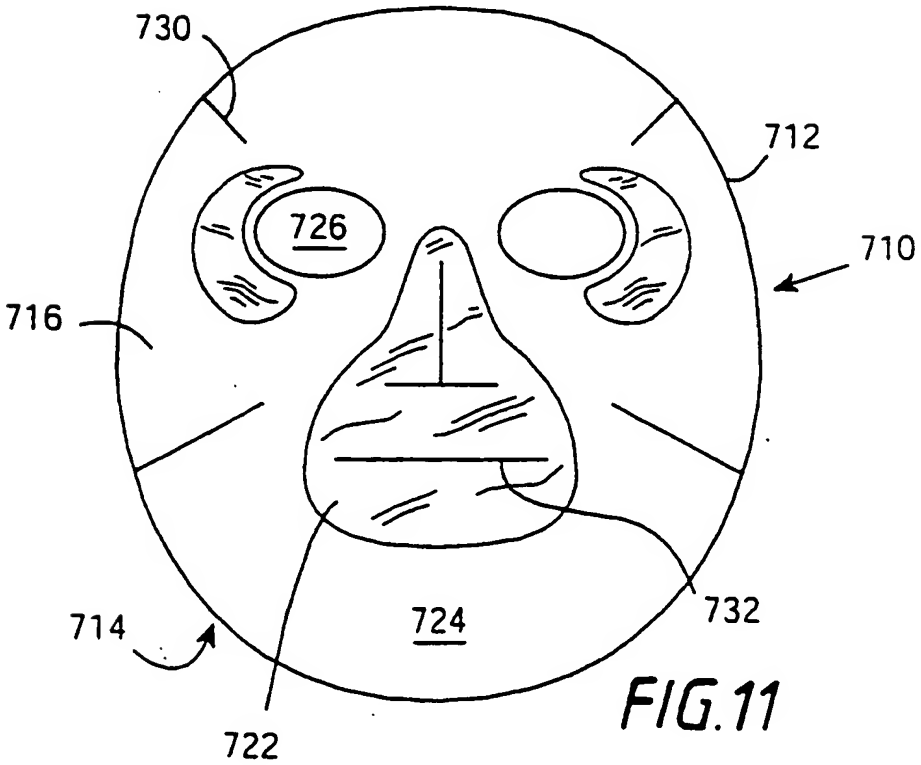



FIG. 11

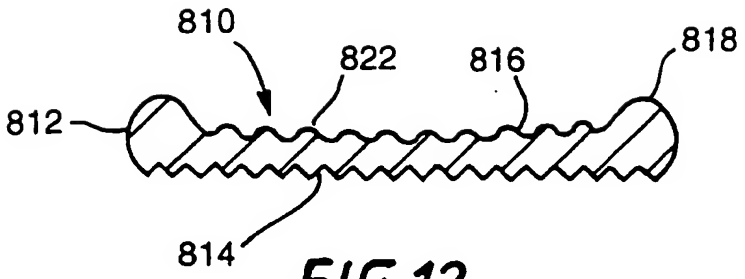



FIG.12

# INTERNATIONAL SEARCH REPORT

Intern. al Application No
PCT/US 00/18108

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K7/48 A61K9/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
CHEM ABS Data, EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| P,X | FR 2 776 518 A (L'OREAL)<br>1 October 1999 (1999-10-01)<br>figure 3 | 1 |
| A | WO 97 06788 A (JANSSEN PHARMACEUTICA N.V.)<br>27 February 1997 (1997-02-27)<br>the whole document | 1 |
| A | US 5 537 687 A (J. GARZA)<br>23 July 1996 (1996-07-23)<br>the whole document | 1 |
| A | WO 97 17044 A (BIOLAMINATIONS PTY, LTD)<br>15 May 1997 (1997-05-15)<br>page 10, line 16-26<br>page 13, line 17-35; claims 1-3 | 1 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 24 October 2000 | 31/10/2000 |

| Name and mailing address of the ISA | Authorized officer |
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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Glikman, J-F |

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# INTERNATIONAL SEARCH REPORT

...rmation on patent family members

Interna al Application No
PCT/US 00/18108

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| | | JP 11342153 A | 14-12-1999 |
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